DELCATH SYSTEMS INC
Form 10-K
March 08, 2011

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, 2010

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 $6.34 per share, was $223,113,918 as of June 30, 2010.

At March 7, 2011, the registrant had outstanding 42,977,787 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2011 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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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the period ended December 31, 2010 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," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K 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, 2010 in Item 1A under "Risk Factors" as well as in Item 7A "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

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

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, Delcath does 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 August 1988. Our corporate offices are located at 810 Seventh Avenue, 35th Floor, New York, New York 10019. Our telephone number is (212) 489-2100.

Overview

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Since our inception, the Company has directed its research efforts towards the development and clinical

study of the Delcath chemosaturation system.

Our initial focus is on cancers in the liver. Currently, the Delcath chemosaturation system is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver while limiting the systemic exposure of this agent. The Company believes that the Delcath chemosaturation system is a platform technology that 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.

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 chemosaturation system delivers high doses of anti-cancer agents (currently melphalan) directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The Delcath chemosaturation system involves a series of three catheter insertions, each of which is made through standard interventional radiology techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs.

In December 2010, the Company submitted its §505(b)(2) New Drug Application (NDA) to the United States Food and Drug Administration (FDA). 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. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

On February 22, 2011 the Company announced that it had received a Refusal to File letter from the FDA for its NDA. Delcath submitted a meeting request to the FDA and intends to meet with the FDA at the earliest opportunity to discuss the issues raised and to confirm our understanding of the remedies required for the resubmission of the filing. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application.

In December 2010, the Company also submitted a CE Mark Technical File to our European Notified Body to obtain CE Mark approval for the Delcath chemosaturation system, which the Company intends to market in the European Economic Area (EEA) as the Delcath Hepatic ChemoSAT™ Delivery System. The Company is seeking approval as a Class III medical device with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver, with subsequent extracorporeal filtration of the regional (hepatic) venous blood.

Before the Company can market the Delcath chemosaturation system in the United States, Delcath must obtain FDA approval of the drug and apparatus under a §505(b)(2) NDA. Similarly, before the Company can market the Delcath chemosaturation system within the EEA, we must obtain CE Mark approval. The Delcath chemosaturation system is currently not approved by any regulatory agency and it cannot be marketed in the United States, EEA or elsewhere without applicable regulatory approval.

At December 31, 2010, the Company had $47.1 million in cash, cash equivalents and certificates of deposit. Since our inception, the Company has raised approximately $125.5 million in aggregate funds (net of expenses). The Company has used approximately $56.6 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 $114.6 million. Since 2006, we have accelerated our investment in and expanded the scope of our clinical trials. For the years ended December 31, 2010, 2009, and 2008, we invested $17.6 million, $9.6 million, and $5.4 million, respectively on research and development activities.

Strategy

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

Our strategy includes the following elements:

- Obtain a CE Mark for the Delcath chemosaturation system for the percutaneous delivery of chemotherapeutic agent (melphalan hydrochloride) to the liver. In December 2010, we submitted a Technical File to our Notified Body in the European Union (EU). Our application is currently under review and the Company expects CE Mark approval for the device in mid-2011. CE Mark approval will allow us to market and sell the system in the EEA.

- Obtain FDA approval for use of the Delcath chemosaturation system in combination with melphalan to treat metastatic melanoma in the liver. In December 2010, the Company submitted our §505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver. In

February 2011, the Company received a Refusal to File letter from the FDA for its NDA. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application.

- Commercialize the Delcath chemosaturation system in the European Economic Area. If we obtain CE Mark approval for the Delcath chemosaturation system, the Company intends to pursue a two-pronged commercialization strategy in the EEA under which Delcath will directly market the Delcath chemosaturation system in certain markets and enter into agreements with third-party distributors in others.

- Commercialize the Delcath chemosaturation system in the United States. If we obtain FDA approval of our NDA, the Company intends to market the Delcath chemosaturation system with melphalan hydrochloride 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. The Company continues to pursue strategic partners to develop certain Asian markets including China, Korea and Japan, In the United States, the Company intends to pursue pharmaceutical partners to co-develop and fund other indications for the Delcath chemosaturation system.

- Obtain approval to market the Delcath chemosaturation system in the United States for the treatment of other cancers in addition to metastatic melanoma in the liver. The Company recently concluded a multi-arm Phase II trial to evaluate the Delcath chemosaturation system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, primary liver cancer and melanomas in the liver that received certain

prior regional treatment with melphalan. Upon successful conclusion of the related clinical trials, Delcath intends to apply for regulatory approval of additional indications.

- Expand the application of the Delcath chemosaturation system. The Company intends to evaluate melphalan and other drug candidates for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions.

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 569,490 deaths and 1.5 million new cases diagnosed in 2010. 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 great for patients, their families and society. The National Institutes of Health estimates the overall costs of cancer in the United States were $263.8 billion in 2010, including $102.8 billion for direct medical costs, $20.9 billion for indirect morbidity costs attributable to lost productivity due to illness and $140.1 billion for indirect mortality costs attributable to lost productivity due to premature death.

Liver Cancer—Prevalence, 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 2010," 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 the 2008 American Cancer Society "Global Cancer Facts & Figures 2nd Edition," liver cancer is the fifth leading cause of cancer death in men and the seventh leading cause among women worldwide. In 2008, there were estimated to be 748,300 new liver cancer cases worldwide and 695,500 people worldwide were projected to die from liver cancer.

There are two forms of liver cancer: primary and metastatic. Primary liver cancer, or hepatocellular carcinoma, originates in the liver and is particularly prevalent in populations where the primary risk factors for the disease (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 primary biological function of the liver, including 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 in the liver is melanoma (cutaneous and ocular). 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 68,130 and 2,480 cases per year, respectively, and we believe approximately 10%-15% of cutaneous and 75%-90% of ocular cases primarily metastasize to the liver. Once melanoma has spread to the liver, currently approved treatment options have been limited and generally ineffective.

In 2010, we concluded a Phase III clinical trial for the Delcath chemosaturation system with melphalan hyrdrochloride in patients with metastatic ocular and cutaneous melanoma to the liver. The Company intends to seek an indication for

the treatment of these types of liver cancers from the FDA. In the EEA, we are currently seeking CE mark approval for our device for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver.

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.

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 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 (1-2 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 permiting 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. The Delcath chemosaturation treatment 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.

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 cancer 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 us 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 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 met the study's primary endpoint of extended hepatic progression-free survival, or hPFS. These results were based on an independently corroborated intent-to-treat analysis. Comparing the treatment with the Delcath system with melphalan to best alternative care, based on independent core lab review of patient scans, the statistical analysis revealed that the Delcath chemosaturation system with melphalan patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the best alternative care control arm. This reflects a 144-day prolongation of hPFS over that of the best alternative care control arm, with less than half the risk of progression and/or death in the Delcath chemosaturation system with melphalan group compared to the best alternative care control group.

Phase II Trial

In addition to the Phase III metastatic melanoma clinical trial, the Company recently 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 islet cell tumors), hepatocellular carcinoma (primary liver cancer), ocular or cutaneous melanoma (eye or skin cancer who have been previously treated with regional therapy using melphalan), and metastatic adenocarcinoma (glandular cancer).

Other Clinical Trials
Delcath intends to evaluate melphalan and other drug candidates for use with the Delcath chemosaturation system to treat other liver cancers, other organs and body regions. The Company will need to conduct additional clinical trials and seek additional approvals for each new indication for our system.

Strategic Alliances

Delcath continues to pursue strategic partners to develop markets in China, Korea and Japan. Asia represents a potentially large market for the Delcath chemosaturation system, accounting for approximately 80% of the world's liver cancer patients. In exchange for granting exclusive distribution rights within the respective geographies, the Company expects to receive substantial upfront cash payments, multi-year minimum purchase commitments and funding for completion of clinical trials from each potential partner. 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.

The Company believes 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, Delcath also intends to pursue United States pharmaceutical partners to co-develop and fund possible additional indications for the Delcath chemosaturation system.

Sales and Marketing

United States
If we obtain FDA approval, the Company intends to market the Delcath chemosaturation system in the United States through a direct sales force and focus our initial marketing efforts on major cancer centers beginning with those hospitals that participated in our Phase III clinical trial. The Company plans to focus our efforts on three distinct groups of medical specialists in these comprehensive cancer centers:

- surgeons who administer the Delcath chemosaturation system;
- oncologists who have primary responsibility for cancer patients; and
- interventional radiologists who are physicians specialized in working with catheter-based systems.

European Economic Area
If we obtain CE Mark approval, the Company intends to pursue a two-pronged commercialization strategy in the EEA under which the Delcath chemosaturation system will be directly marketed in certain markets and the Company intends to enter into agreements with third-party distributors in others.

Delcath has applied for a Class III medical device CE Mark, which if received, will allow us to market and sell the Delcath chemosaturation system in the EEA. The EEA consists of the twenty-nine member countries of the EU, as

well as Lichtenstein, Iceland, and Norway. The Company intends to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. These countries represent approximately 85%-90% of the total potential liver cancer market in the EEA. Delcath plans to establish a direct sales force in the United Kingdom, Germany and the Netherlands and utilize distributors in France, Italy, and Spain.

Under the regulatory scheme in the EEA, we have applied for CE Mark approval and, if approved, the Delcath chemosaturation system will be approved for marketing as a device only. Melphalan hydrochloride is currently available in 14 member states of the EEA, including the six countries we are initially targeting. Doctors will separately obtain melphalan for use with the Delcath chemosaturation system. In the future, we intend to enter into a third party supply agreement for the manufacture of melphalan and apply for regulatory approval of the drug for use specifically with our chemosaturation system in the EEA. If we obtain approval for our labeled melphalan, we intend to market the drug and device together in the EEA.

Third-Party Reimbursement

Because the Delcath chemosaturation system is characterized by the FDA as an experimental drug/device combination product, it is not currently reimbursable in the United States. After it is approved by the FDA, the Company will seek to have third-party payors reimburse the cost of the Delcath chemosaturation system and the associated procedures. In the United States, third-party payors consist of government programs, such as Medicare, Medicaid, private health insurance plans, managed care organizations and other

similar programs. Three factors are key to the reimbursement of any product:

- Coding, which ensures uniform descriptions of the procedures, diagnoses and medical products involved;
- Coverage, which is the payor's policy describing the clinical circumstances under which it will pay for a given treatment; and
- Payment processes and amounts.

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 medical coding and 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 reimbursement.

In the United States, prior to FDA approval the Company intends to apply for a Current Procedural Terminology (CPT) Category III code. Delcath will seek to convert to a Category I code following FDA approval and upon meeting the requirements for conversion. The Company also intends to apply for new ICD-9/10 (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 procedures in current DRGs.

In Europe, Delcath is subject to similar regulatory and legislative reimbursement challenges. 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.

Government-sponsored initiatives to reform healthcare and reduce costs are ongoing in the United States and other foreign countries. Third-party payors are also increasingly adjusting reimbursement 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 plans to assemble, sterilize and package the Delcath chemosaturation system at our facility in Queensbury, New York. Delcath currently utilizes contract manufacturers to manufacture the components of the Delcath chemosaturation system. The Delcath chemosaturation system 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 sale and Delcath relies on third-party vendors to perform the sterilization process.

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. Our 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 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.

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 the FDA, other regulatory agencies, and their respective foreign equivalents. 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 products. The Delcath system will also be subject to extensive regulation by foreign governments if marketed abroad, whether or not the Company has obtained FDA approval for a given product and its uses.

Government regulation substantially increases the cost of researching, developing, manufacturing and selling medical device and pharmaceutical products. The regulatory review and approval process, which includes pre-clinical testing and clinical trials of our product, is lengthy, expensive and uncertain. The Company must obtain regulatory approval for the Delcath chemosaturation system from each country in which we intend to sell, 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 the product's safety, efficacy, potency and purity for each intended use. Moreover, approval policies or regulations may change.

The Delcath chemosaturation system is regulated as a drug in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. As such, FDA approval of the Delcath chemosaturation system is required before any commercial distribution may commence in the United States.

In December 2010, we submitted our §505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver. Melphalan hydrochloride, the drug Delcath is 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 the Company used in its 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, Delcath will be seeking a revised label of melphalan for use with the Delcath chemosaturation system through a §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. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

In February 2011, the Company announced that it had received a Refusal to File letter from the FDA for its NDA. Delcath has submitted a meeting request to the FDA and intends to meet with the FDA at the earliest opportunity to discuss the issues raised and to confirm our understanding of the remedies required for the resubmission of the filing. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application.

Upon resubmission of our application, the FDA normally performs a cursory review to assess whether the NDA is sufficiently complete to warrant a substantive review. If the FDA agrees to formally file the application, they will

issue a Prescription Drug User Fee Act (PDUFA) action date. 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.

The Company intends to request a Priority Review in our resubmitted NDA to the FDA. The approval of the Delcath chemosaturation system may take longer than anticipated if the FDA requests additional information or clarification, or if any major amendments to our application are requested. In addition, the FDA may refer this application to an advisory committee of experts. This process is referred to as a "panel review," and could delay the review of the Delcath chemosaturation system.

When the FDA is prepared to issue a marketing application action letter upon completion of a review cycle, it will issue either an "approval letter" or a "complete response" letter to the applicant. If the FDA's evaluation of the application, clinical studies and study sites and manufacturing facilities are favorable, the FDA will issue the "approval letter". The FDA sends the "complete response" letter to applicants to indicate that the review cycle for an application is complete and that the application is not ready for approval in

its current form. The "complete response" letter contains a list of information that must be submitted or conditions that must be met to obtain approval of the application.

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

Orphan Drug Regulation

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

Foreign Regulation

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

The EEA has an agreement between member states of the European Free Trade Association (EFTA), the European Community (EC), and all member states of the European Union (EU) regarding certain certifications for medical devices. The CE marking (also known as CE mark) is a mandatory conformity mark on many products placed on the single market of the EEA. The CE marking does not certify that a product has met EU consumer safety, health or environmental requirements, but can permit the marketing of a medical device once obtained. CE Marking is an indication that a medical device complies with the essential requirements of applicable medical device directives, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark allows a company to market and sell its medical device in countries in the EEA.

In December 2010, the Company submitted a CE Mark Technical File to its European Notified Body for the Delcath chemosaturation system to obtain CE Mark approval for our proprietary chemosaturation system, which Delcath intends to market in the EEA as the Delcath Hepatic ChemoSAT Delivery System. The Company is seeking approval as a Class III medical device with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. The CE Mark review process continues and the Company expects CE Mark approval in mid-2011.

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.

Employees

As of December 31, 2010, the Company had 47 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

You should carefully consider the risks described below together with the other information included in this Annual Report on Form 10-K. Our business, financial condition, liquidity and results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock could decline.

Risks Related to Our Business and Financial Condition

If the Company is not successful in developing and obtaining regulatory approval of the Delcath chemosaturation system, or if the Company is unable to market and sell the system, Delcath 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 approvals of this product and currently we have only developed this system for the treatment of liver cancer with melphalan. If the Delcath chemosaturation system with melphalan fails as a

commercial product, we have no other products to sell.

Continuing losses may exhaust our capital resources.

At December 31, 2010, the Company had $47.1 million in cash, cash equivalents and certificates of deposit. The Company has had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. Delcath expects to incur losses while generating minimal revenues over the next year. From our inception on August 5, 1988 through December 31, 2010, the Company has incurred cumulative net losses of approximately $114.6 million. For the years ended December 31, 2010, 2009 and 2008, Delcath incurred net losses of approximately $46.7 million, $22.1 million and $6.9 million, respectively. To date, Delcath has funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings. If Delcath continues 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 the Company cannot raise the additional capital that may be required to commercialize the Delcath chemosaturation system, our potential to generate future revenues will be significantly limited even if Delcath receives FDA approval and/or foreign regulatory approvals, and if Delcath cannot raise additional capital generally, our business operations will be harmed.

The FDA has informed us that the Delcath chemosaturation system with melphalan will be regulated as a drug. Before the Company can obtain approval to sell our product commercially in the United States, we will need approval from the FDA. Delcath will also need approval to market our products in foreign markets. The Company has submitted a §505 (b)(2) NDA to the FDA and a CE Mark application to our Notified Body in the EU, but currently the Delcath chemosaturation system has not been approved by the FDA or any foreign regulatory authority. If the Company obtains approval, we may require additional financing to commercialize our product in the United States and foreign markets. The Company does not know if additional financings will be available when needed, or if they are available, that they will be available on acceptable terms. If Delcath is unable to obtain additional financing as needed, we may not be able to complete our trials, obtain regulatory approvals or sell the Delcath chemosaturation system commercially.

Our liquidity and capital requirements will depend on numerous factors, including:

- our research and product development programs, including clinical studies;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- Timing of product commercialization activities, including marketing arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our research and development and commercialization activities.

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

Some of the information contained in this Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may," "intend," "plan," "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. You should read statements that contain these words carefully because they:

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

The Company believes it is important to communicate our expectations. However, there may be events in the future that the Company is not able to accurately predict and/or over which we have no control. The risk factors listed in this section, other risk factors about which we may not be aware, as well as any cautionary language in this Annual Report on Form 10-K provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations described in our forward-looking statements. You should be aware that the occurrence of the events described in these risk factors could have an adverse effect on our business, results of operations and financial condition.

Risks Related to FDA and Foreign Regulatory Approval

The development and approval process may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system. Delcath does not have, and may never obtain, the regulatory approvals needed to market our product. Our failure to obtain, or delays in obtaining, regulatory approvals would 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, other regulatory agencies, and their respective foreign equivalents. 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. The Delcath system will also be subject to extensive regulation by foreign governments if marketed abroad, whether or not FDA approval has been obtained for a given product and its uses.

Government regulation substantially increases the cost of researching, developing, manufacturing and selling pharmaceutical products. The regulatory review and approval process, which includes pre-clinical testing and clinical trials of our product, is lengthy, expensive and uncertain. Delcath must obtain regulatory approval 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 the product's safety, efficacy, potency and purity for each intended use. Moreover, approval policies or regulations may change.

In December 2010, the Company submitted a CE Mark Technical File to our European Notified Body for the Delcath chemosaturation system to obtain CE Mark approval for our proprietary chemosaturation system, which Delcath intends to market in the European Economic Area, or EEA. The Company expects CE Mark approval in mid-2011. In December 2010, the Company also submitted our §505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, the Company received a Refusal to File letter from the FDA for its NDA. Delcath has submitted a meeting request to the FDA and intends to meet with the FDA at the earliest opportunity to discuss the issues raised and to confirm our understanding of the remedies required for the resubmission of the filing. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application. If Delcath resubmits the NDA and subsequently receives a second Refusal to File letter from the FDA, or, if it is accepted but the Company does not obtain FDA approval, our ability to commercialize the Delcath chemosaturation system in the United States will be materially limited and the value of the Company and our results of operations will be harmed.

The Company will not be able to commercialize the Delcath chemosaturation system until Delcath obtains FDA approval in the United States, CE Mark approval in the EEA or approval by comparable authorities in other countries. The development and approval process takes many years, requires 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 any products that Delcath develops;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our receipt of revenues.

If the Company does not obtain required approvals, Delcath may not be able to export or sell the Delcath chemosaturation system outside the U.S. market, which will limit our sales opportunities.

In December 2010, the Company submitted a CE Mark Technical File to our European Notified Body to obtain CE Mark approval for our proprietary chemosaturation system. In Europe, we expect the system to be regulated as a device, and the CE mark application covers the device only. If Delcath does not receive CE Mark approval for the Delcath chemosaturation system, we will not be able to sell the Delcath chemosaturation system in the EEA or export the Delcath chemosaturation system from the United States for marketing in the EEA.

In addition, regulatory approval is required before the Company can market the Delcath system in other parts of the world. If the FDA does not approve our applications or Delcath is not able to obtain approval from one or more other countries where we would like to sell the Delcath chemosaturation system, the Company will be unable to market the Delcath chemosaturation system as intended. If the Company is unable to market the Delcath system internationally because of an inability to obtain and maintain required approvals, our international market opportunity will be materially limited and the value of our company and our results of operations will be harmed.

If the Company does not obtain regulatory approval for the Delcath chemosaturation system with melphalan or other chemotherapeutic agents, Delcath will not be able to market or sell the system in the United States.

The FDA has informed us that the Delcath chemosaturation system with melphalan or other chemotherapeutic agents will be regulated as a drug and we cannot sell or market the Delcath chemosaturation system with melphalan or other chemotherapeutic agents without FDA approval. Although melphalan and other drugs have been FDA approved as chemotherapeutic agents, regulatory approval is required in the United States for the apparatus and associated drug including the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system, which is substantially higher than prior approved doses of melphalan and such other drugs. If Delcath does not obtain and maintain regulatory approval for our use of melphalan or other chemotherapeutic agents, the value of our company and our results of operations will be harmed.

Even if the FDA grants approval of the Delcath chemosaturation system for the indications we intend to request, our ability to market the Delcath chemosaturation system would be limited to those uses, and Delcath will be subject to significant ongoing regulatory obligations and oversight.

Even if the FDA grants approval for use of the Delcath chemosaturation system with melphalan in the treatment of ocular and cutaneous melanoma that has metastasized to the liver, our ability to market and promote the Delcath chemosaturation system in the United States would be limited to its indication for use with that drug in treating that disease. If the Company is unable to obtain FDA approval or successfully market the Delcath chemosaturation system for treatment of other diseases, organs and regions and with other drugs, our ability to generate revenue and grow will be limited. FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product, may require that the Company conduct costly post-marketing surveillance and ongoing post-marketing studies. Material changes to an approved product, such as manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. If Delcath or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;
- warning letters;
- fines;
- import or export restrictions;
- product recalls or seizures;
- injunctions;
- total or partial suspension of clinical trials or production;
- civil penalties;
- withdrawals of previously approved marketing applications or licenses;
- recommendations by the FDA or other regulatory authorities against entering into governmental contracts with us; or
- criminal prosecutions.

If future clinical trials are unsuccessful or significantly delayed, or if the Company does not complete our clinical trials, Delcath may not be able to market the Delcath chemosaturation system for other indications.

The Company may be required to provide the FDA and similar foreign regulatory authorities with pre-clinical and clinical data to demonstrate that the Delcath chemosaturation system is safe and effective for each indication before it can be approved for commercialization. The pre-clinical testing and clinical trials of our chemosaturation system with melphalan or any other chemotherapeutic agent or compound the Company uses in our system must comply with the regulations of numerous federal, state and local government authorities in the United States, principally the FDA, and by similar agencies in other countries. Clinical development is a long, expensive and uncertain process and is subject to delays. The Company may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials.

In 2010, the Company 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 recently completed a multi-arm Phase II clinical trial of the Delcath system with melphalan in patients with primary and metastatic melanoma stratified into four arms. Our Phase III metastatic melanoma clinical trial has successfully met the study's primary endpoint of extended hPFS in patients with melanoma metastases to the liver. Delcath intends to conduct other clinical trials for other indications, and it may take several years to complete the testing of the Delcath chemosaturation system with melphalan, other chemotherapeutic agents or other compounds for use in the treatment of the indications Delcath wishes 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 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 may request additional clinical trials relating to our NDA submissions;

- the FDA 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.

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

Delcath designs 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. Accordingly, Delcath may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. Although the Company relies 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, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, 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. Our reliance on third parties does not relieve us of these responsibilities and requirements, and we may fail to obtain regulatory approval for the Delcath chemosaturation system if these requirements are not met.

Third-party reimbursement may not be available to purchasers of the Delcath chemosaturation system or may be inadequate, resulting in lower sales even if FDA or other foreign regulatory approval is granted.

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

The Delcath chemosaturation system is currently not approved by the FDA. Medicare, Medicaid and private health insurance plans will not reimburse its use in the United States due to the currently unapproved nature of the product. Delcath will seek reimbursement by third-party payors of the cost of the Delcath system after its use is approved by the FDA. The Company has applied for, but has not yet received CE mark approval for the Delcath chemosaturation system. Without such approval, third-party payors and government health agencies of member states of the EEA will not reimburse its use. If we obtain CE mark for the Delcath chemosaturation system, Delcath also intends to seek third party or government reimbursement within those countries within the EEA where we expect to market and sell the Delcath chemosaturation system. There are no assurances that third-party payors in the United States or abroad 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 for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies.

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

The Company purchases components for the Delcath chemosaturation system from third parties, some of which are sole-source suppliers.

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

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 of the Delcath chemosaturation system on file with the FDA, certain foreign regulatory agencies and meet cGMP, or current good manufacturing practice, 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 fail to meet those regulatory obligations, the Company 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 Delcath needs 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.

If the Company 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.

The Company has entered into a manufacturing and supply agreement with Synerx Pharma, LLC (Synerx) and Bioniche Teoranta, an affiliate of Mylan, Inc. (Bioniche), for the supply of our branded melphalan hydrochloride for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. Delcath intends 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 system, as well as for labeling and finishing services. Delcath 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 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 Delcath is unable to obtain sufficient melphalan and labeling services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our current and future suppliers, our business, financial condition, and results of operations may be materially harmed.

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, the Company may be unable to successfully commercialize our product in the EEA.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system will be approved for marketing as a device only, and doctors will separately obtain melphalan for use with the Delcath chemosaturation system. Although melphalan hydrochloride 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.

In the future, we intend to enter into a third party supply agreement for the manufacture of melphalan and apply for regulatory approval of the drug for use specifically with our chemosaturation system in the EEA. There can be no assurance that we will be able to enter into a supply agreement for melphalan in the EEA or that the terms and conditions of any agreement will be favorable to Delcath or that Delcath will receive regulatory approval for its labeled melphalan in the EEA.

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

Our ability to conduct timely clinical trials to obtain regulatory approval for and commercialize the Delcath chemosaturation system depends on our ability to manufacture the system, including the chemotherapeutic agents or other compounds, either directly or through third-parties, in accordance with FDA and other regulatory requirements. Delcath intends to assemble, sterilize and package the Delcath system at our Queensbury, NY facility and will rely on third-party suppliers for a number of components of our system, including melphalan. The Company has a limited manufacturing history and we may not be able to manufacture the system in commercial quantities or in a cost-effective manner. In addition, Delcath 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 system to purchasers. Further, if our Queensbury, NY facility fails to obtain or maintain approvals under ISO 13485 and FDA

cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated.

The Company does not have written contracts with all of our suppliers for the manufacture of components for the Delcath chemosaturation system.

Delcath does not have written contracts with all our suppliers for the manufacture of components for the Delcath chemosaturation system and if we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, the commercialization of the Delcath chemosaturation system could be delayed and we may not be able to manufacture the system in commercial quantities or in a cost-effective manner. Certain components, however, are available from only a limited number of sources. Components of the Delcath system are currently manufactured for us in small quantities for use in our preclinical and clinical studies. Delcath will require significantly greater quantities to commercialize the product. The Company may not be able to find alternate sources of comparable components. If Delcath is 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 could be delayed.

Delcath has limited experience in marketing products, and as a result, the Company may not be successful in marketing and selling the Delcath chemosaturation system even if we receive FDA or other foreign regulatory approvals.

Delcath has not previously sold, marketed or distributed any products. In order to commercialize the Delcath chemosaturation system or any other product successfully, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The Company intends to develop our own sales force to market our products in the United States, but we have limited experience in building a sales and marketing organization. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If Delcath cannot successfully develop the infrastructure to market and commercialize the Delcath chemosaturation system, our ability to generate revenues may be harmed, and Delcath 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. Outside the United States the Company intends to market our products primarily through strategic partners and distributors except in a few specific foreign countries within the EEA where the Company intends to market the Delcath chemosaturation system on a direct basis. If Delcath is not able to collaborate with an alliance partner to market our products outside of the United States, our efforts to commercialize the Delcath chemosaturation system or any other product may be less successful.

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

In addition to a research and distribution agreement the Company entered into with Chi-Fu Trading Co., Ltd., a Taiwanese company, on February 9, 2010, Delcath intends to enter into one or more strategic alliances to further address markets outside the United States and to help fund the development of additional indications or for use with additional chemotherapy agents within the United States. The Company may not be able to enter into any additional alliances on acceptable terms, if at all, and may face competition in our search for alliances. Our collaborative relationships may never result in the successful development or commercialization of the Delcath chemosaturation system or any other product or the generation of revenue.

The success of any collaboration will be dependent upon the commitment of our collaborators and the timely performance of their obligations, both of which are beyond our control. The terms of any such 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. In addition, any third parties with which Delcath collaborates 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. Delcath is 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. The Company 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 Delcath does not receive CE Mark Approval, or our commercialization strategy is not successful in the European Economic Area, the Company will not be able to commercialize or sell the Delcath chemosaturation system in the European Economic Area.

The Company has applied for CE Mark approval in order to market the Delcath chemosaturation system in the EEA. CE Marking is an indication that a medical device complies with the essential requirements of applicable medical device directives, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark will allow us to market and sell the Delcath chemosaturation system in countries in the EEA. If Delcath does not receive CE Mark approval, we will be prohibited from selling the Delcath chemosaturation system in the EEA.

If Delcath receives CE Mark approval, we intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly market the Delcath chemosaturation system in certain markets and enter into agreements with third-party distributors in others. Delcath currently has no sales, marketing, commercial, or distribution capabilities in any countries in the EEA. If Delcath is unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our product candidate receives marketing approval in the EEA, we will not be able to successfully sell our product there. In addition, Delcath may not be able to hire the qualified sales and marketing personnel we need or be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all.

Market acceptance of the Delcath chemosaturation system will depend on substantial efforts within the healthcare arena.

Market acceptance of the Delcath chemosaturation system will depend upon a variety of factors including:

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

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

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

The loss of key personnel could adversely affect our business.

The loss of a member of our senior executive staff could delay our obtaining FDA approval, our introducing the Delcath chemosaturation system commercially and our generating revenues and profits. Competition for experienced personnel is intense. If Delcath cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

Risks Related to Patents, Trade Secrets and Proprietary Rights

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

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if Delcath is successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the

healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies the Company has patented, licensed or developed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that Delcath will receive a favorable outcome in any such litigation. If a third party claims that Delcath infringed its patents, any of the following may occur:

- Delcath may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- Delcath may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If others file patent applications with respect to inventions for which Delcath already has patents issued to us or have patent applications pending, the Company may be forced to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, Delcath may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath chemosaturation system or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Certain of our United States and foreign patents have already expired and other United States patents relating to the Delcath chemosaturation system will expire beginning in 2012 through 2016.

Similar considerations apply in any other country where the Company is prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Risks Related to Products Liability

If product liability lawsuits are brought against us, the Company might incur substantial liabilities and could be required to limit the commercialization of the Delcath chemosaturation system.

Our business exposes us to potential liability risks that may arise from the testing, manufacture, marketing and sale of our system. In addition, because the Delcath chemosaturation system is intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits. The Company may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the use of our system, the patient may be injured through the use of our system, which may subject us to claims. If Delcath is involved in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and might result in adverse publicity, regardless of the ultimate outcome of the litigation.

The Company may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Clinical trials, manufacturing and product sales may expose us to liability claims from the use of the Delcath chemosaturation system. Were such a claim asserted Delcath would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition and results of operations. Delcath currently carries product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to an Investment in Our Securities

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

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

- results of our clinical trials;
- regulatory delays, non-acceptance or non-approval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the Delcath chemosaturation system;
- product recalls;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;

- a challenge to one of our patents, either in court or via administrative proceedings in the United States Patent and Trademark Office;
- conditions generally affecting the healthcare and cancer treatment industries; and
- the success of our operating strategy.

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

The market price of our common stock has historically been volatile. During the three years ended December 31, 2010, the range of the high and low last reported sales prices of our common stock on The NASDAQ Capital Market have ranged from a high of $16.18 (during the fiscal quarter ended June 30, 2010) to a low of $0.87 (during the fiscal quarter ended December 31, 2008). During the 12 months ended December 31, 2010, the range of the high and low last reported sales prices of our common stock have ranged from a high of $16.18 (during the fiscal quarter ended June 30, 2010) to a low of $4.31 (during the fiscal quarter ended March 31, 2010). Sales of substantial amounts of common stock, or the perception that such sales could occur, could have an adverse effect on prevailing market prices for our common stock.

Our insiders beneficially own a significant portion of our stock.

As of December 31, 2010, our executive officers, directors and affiliated persons beneficially owned approximately 7.0% of our common stock. As a result, our executive officers, directors and affiliated persons will have significant influence to:

- elect or defeat the election of our directors;
- amend or prevent amendment of our certificate of incorporation or by-laws;
- effect or prevent a merger, sale of assets or other corporate transaction; and
- affect the outcome of any other matter submitted to the stockholders for vote.

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

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.

The warrants issued in our September 2007 and June 2009 private placements contain anti-dilution provisions. The September 2007 warrants are subject to "full ratchet" protection upon certain equity issuances below $3.44 per share (as may be further adjusted). The June 2009 warrants are subject to an exercise price adjustment upon certain equity issuances below $3.60 per share (as may be further adjusted). In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

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

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

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

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

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

Our common stock is listed on The NASDAQ Capital Market.

If the Company fails to meet the requirements of The NASDAQ Capital Market for continued listing, our common stock could be delisted. To keep such listing, Delcath is required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float,

(iii) a certain number of round lot shareholders, and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million. Delcath is presently in compliance with these requirements.

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

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

If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

The Company has never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

Delcath currently intends to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that Delcath may enter into or by the terms of any preferred stock that we may authorize and issue. Delcath does not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

As of December 31, 2010, the Company had an aggregate of 26,971,850 shares of common stock authorized but unissued. Subject to certain volume limitations imposed by The NASDAQ Capital Market, Delcath may issue all of these shares without any action or approval by our shareholders. Delcath may expand our business through complementary or strategic acquisitions of other companies and assets, and we may issue shares of common stock in connection with those acquisitions or otherwise. Any shares issued in connection with these activities, the exercise of stock options or otherwise would dilute the percentage ownership held by our investors.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices currently occupy 17,320 square feet of office space at 810 Seventh Avenue, New York, New York under a lease that expires in November 2020. In addition, the Company leases two buildings containing approximately 10,320 square feet at 566 Queensbury Avenue and 8,000 square feet at 2 Country Club Road in Queensbury, New York. These buildings house manufacturing, research and development, and office space each under lease agreements that expire on August 31, 2012 and November 12, 2012, respectively. Delcath has an option to purchase the building at 566 Queensbury Avenue prior to the expiration of the lease term. The Company believes substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs.

Item 3. Legal Proceedings.

None.

Item 4. Removed and Reserved.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on The NASDAQ Capital Market under the symbol "DCTH".

The following table sets forth the high and low last reported sales prices of our common stock for the fiscal quarters indicated as reported on The NASDAQ Capital Market:

Common Stock Price Range

	2010	
	High	Low
Quarter ended March 31, 2010	$8.41	$4.31
Quarter ended June 30, 2010	16.18	6.34
Quarter ended September 30, 2010	8.69	5.53
Quarter ended December 31, 2010	11.27	7.20

	2009	
	High	Low
Quarter ended March 31, 2009	$1.95	$1.18
Quarter ended June 30, 2009	3.98	1.78
Quarter ended September 30, 2009	5.05	2.81
Quarter ended December 31, 2009	6.19	4.02

On March 7, 2011 there were 60 stockholders of record of our common stock.

Dividend Policy

The Company has never declared or paid cash dividends on our common stock and has no intention to do so in the foreseeable future.

Recent Sales of Unregistered Securities

The Company did not sell any equity securities that were not registered under the Securities Act of 1933, as amended, in the quarter ended December 31, 2010.

Performance Graph

The following graph compares the cumulative total stockholder return on our common stock over the five-year period ended December 31, 2010, the cumulative total return during such period of the NASDAQ Composite Index and the Hemscott Industry Group 513-Drug Delivery. The comparison assumes $100 was invested on December 31, 2005, in our common stock and in each of the foregoing indices and assumes reinvestment of dividends. The stock performance shown on the graph below represents historical stock performance and is not necessarily indicative of future stock price performance.

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	12/05	12/06	12/07	12/08	12/09	12/10
Delcath Systems Inc.	100.00	108.82	54.41	35.00	150.29	288.24
NASDAQ Composite	100.00	111.74	124.67	73.77	107.12	125.93
Industry Group 513 - Drug Delivery	100.00	89.71	100.82	49.80	72.02	85.99

Item 6. Selected Financial Data.

The selected financial data set forth below should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included in this Annual Report on Form 10-K.

The selected financial data set forth below as of December 31, 2010 and 2009 and for the years ended December 31, 2010, 2009 and 2008 are derived from our audited financial statements included in this Annual Report on Form 10-K. All other selected financial data set forth below is derived from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our results of operations to be expected in the future.

	Year Ended December 31,				
(Dollars in thousands)	2010	2009	2008	2007	2006
Statement of Operations Data					
Costs and expenses	$30,743	$13,536	$8,066	$6,913	$11,699
Operating loss	30,743	13,536	8,066	6,913	11,699
Net loss	46,684	22,057	6,865	3,664	10,952
Loss per share	(1.20)	(0.82)	(0.27)	(0.16)	(0.55)

	Year Ended December 31,				
(Dollars in thousands)	2010	2009	2008	2007	2006
Balance Sheet Data					
Current assets	$48,898	$36,286	$11,341	$18,091	$8,760
Total assets	50,578	36,807	11,359	18,106	8,764
Current liabilities	21,197	13,049	1,152	1,677	670
Stockholder's equity	29,080	23,758	10,207	16,429	8,093

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

The following section should be read in conjunction with Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Annual Report on Form 10-K.

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Since our inception, the Company has directed its research efforts towards the development and clinical study of the Delcath chemosaturation system. Our proprietary system has been designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body.

Our initial focus is on cancers of the liver. Currently, the Delcath chemosaturation system is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver while limiting the systemic exposure of this agent. The Company believes that the Delcath chemosaturation system is a platform technology that 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

The Delcath chemosaturation system provides concentrated regional therapy by isolating the circulatory system of the target organ to directly deliver saturating doses of anti-cancer agents, while limiting the systemic exposure to, and side effects from those agents 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 made through standard interventional techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs.

In December 2010, the Company submitted our §505(b)(2) New Drug Application (NDA) to the United States Food and Drug Administration (FDA), seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver. 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. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

In February 2011, the Company received a Refusal to File letter from the FDA for the NDA. Delcath submitted a meeting request to the FDA and intends to meet with the FDA at the earliest opportunity to discuss the issues raised and to confirm our understanding of the remedies required for the resubmission of the filing. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application. In December 2010, the Company also submitted a CE Mark Technical File to our European Notified Body to obtain CE Mark approval for the Delcath chemosaturation system, which Delcath intends to market in the European Economic Area, or EEA. The Company is seeking approval as a Class III medical device with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver.

Before the Company can market the Delcath chemosaturation system in the United States we must obtain FDA approval of the drug and device under a §505(b)(2) NDA. Similarly, before we can market the Delcath chemosaturation system within the EEA Delcath must obtain CE Mark approval. The Delcath chemosaturation system is currently not approved by any regulatory agency and it cannot be marketed in the United States, EEA or elsewhere without the applicable regulatory approval.

Our expenses generally include costs for regulatory activities, research and development activities, personnel, manufacturing, clinical studies, securing patents, rent for our facilities, and general corporate and working capital, including general and administrative expenses. Because Delcath has no FDA approved product and no commercial sales, we will continue to be dependent upon existing cash, the sale of equity or debt securities, or establishing strategic alliances with appropriate partners to fund future activities. The Company cannot be assured that it will obtain FDA or any other approval for the Delcath chemosaturation system, that it will have, or could raise, sufficient financial resources to sustain our operations pending regulatory approvals, or that, if and when the required approvals are obtained, there will be a market for our product.

The Company expects the amount of capital required to continue navigating the various regulatory pathways, establish a fully operational manufacturing facility in upstate New York, and, if approved, build a commercial operation will continue to increase over the coming months. Delcath believes that we have sufficient capital for operations through 2011. Delcath is a development stage company, and since inception has raised approximately $125.5 million (net of expenses). The Company has financed its operations primarily through public and private placements of equity securities. Delcath has incurred net losses since it was founded and the Company anticipates that losses will continue over the coming year.

Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and anticipates that losses will continue over the coming year. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments. The Company continues to move forward aggressively. As Delcath seeks FDA approval and CE marking of the Delcath chemosaturation system we expect that both our expenses and capital expenditures will increase.

At December 31, 2010, cash and cash equivalents totaled $45.6 million, as compared to $35.5 million at December 31, 2009. Approximately $45.4 million of our funds were invested in money markets at December 31, 2010.

During the twelve months ended December 31, 2010, Delcath used $24.1 million of cash in our operating activities. This amount compares to $10.5 million used in our operating activities during the comparable twelve month period ended December 31, 2009. The increase of $13.6 million, or 129.5%, is primarily due to a significant increase in costs related to our regulatory filings, as well as an increase in compensation related expenses as the Company grew from 17 to 47 employees during 2010. The Company expects that cash allocated to operating activities will continue to increase as Delcath continues to navigate the extensive regulatory processes for both FDA approval and CE marking, continues to outfit and fully staff the manufacturing and research and development facilities in upstate New York and, if regulatory approval is received, begins building out a sales force. The Company believes it has sufficient capital to fund our operating activities through 2011.

At December 31, 2010, the Company's accumulated deficit was approximately $116.1 million, as compared to $69.4 million at December 31, 2009. Because our business does not generate positive cash flow from operating activities, the Company may need to raise additional capital in order to fully commercialize our product or to fund development efforts relating to additional indications. Delcath anticipates that we will be able to raise additional capital in the event that we find it in our best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be

forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

In March 2010, the Company filed a registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The registration statement became effective on April 13, 2010 (333-165677). The Company used this registration statement for its August 2010 public offering detailed in Note 3 of the footnotes to the 2010 financial statements in this Annual Report on Form 10-K. Because the maximum aggregate offering price of all securities registered is $100,000,000, the Company's issuance of any securities, will reduce the amount of other securities that it can issue pursuant to the registration statement on Form S-3.

The Company has funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2009 and 2010, along with our registered direct offerings in 2007 and 2009. As of December 31, 2010, Delcath had approximately $65,000,000 aggregate amount of common stock, preferred stock, stock purchase contracts, warrants and debt securities (or a combination of these securities) available to be issued under our effective registration statement on Form S-3. The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, capital expenditures and working capital. For a detailed discussion of our various sales of securities see Note 3 in the footnotes to the 2010 financial statements in this Annual Report on Form 10-K.

Contractual Obligations, Commercial Commitments and Off-Balance Sheet Arrangements

The Company is obligated to make future payments under various contracts such as long-term research and development agreement obligations and lease agreements. The following table provides a summary of significant contractual obligations at December 31, 2010 (in millions):

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Activities:					
Research Activities	$1.0	$1.0	$-	$-	$-
Operating Leases	10.4	1.1	3.0	3.1	3.2

Delcath's five year CRADA for the development of the Delcath chemosaturation system with the NCI expired on December 14, 2006 and was extended for an additional five years to December 14, 2011. The principal goal of the CRADA is to continue the development of a novel form of regional cancer therapy by designing clinical protocols utilizing the Delcath chemosaturation system to regionally deliver chemotherapeutics to patients with unresectable malignancies confined to an organ or region of the body. Under the five year extension, Delcath pays $1,000,000 per year to the NCI for clinical support. These funds are payable in quarterly amounts of $250,000, and will be used for material support of the CRADA (including equipment, supplies, travel, and other related CRADA support), as well as for support of existing or new scientific or clinical staff to be hired by NCI who are to perform work under the CRADA.

Our operating lease obligations at December 31, 2010 include: the annual rent under the lease for our office space at 810 Seventh Avenue, New York, New York, which will expire in November, 2020 and the annual rent under the leases for our facilities in Queensbury, New York, which expire on August 31, 2012 and November 12, 2012. See Part I, Item 2, "Properties" and Note 5 of the footnotes to the 2010 financial statements in this Annual Report on Form 10-K.

Future Capital Needs; Additional Future Funding

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for our entire history and there can be no assurance that we will ever achieve consistent profitability. The Company believes that its capital resources are adequate to fund operations through 2011, but anticipate that additional working capital may be required to continue our operations. There can be no assurance that such working capital will be available on acceptable terms, if at all.

Results of Operations for the Year Ended December 31, 2010; Comparisons of Results of the Years Ended December 31, 2009 and 2008

Delcath has operated at a loss for its entire history. The Company had a net loss for the year ended December 31, 2010, of $46.7 million, an increase of $24.6 million, or 111.3%, compared to the net loss from continuing operations for the same period in 2009.

This increase is primarily due to a $17.2 million increase in operating costs and a $7.4 million increase in derivative instrument expense, which is a non-cash expense. The increase in operating expenses reflects a significant increase in costs related to our regulatory filings, as well as an increase in compensation related expenses as the Company grew from 17 to 47 employees during 2010. The warrants issued in 2007 and 2009 as part of our sales of common stock are considered to be derivatives and are subject to valuation and adjustment on a quarterly basis (see item 7A, below for a complete description). This mark-to-market adjustment of the warrant valuation resulted in the recording of $15.95 million in derivative instrument expense for the year ended December 31, 2010; a $7.4 million increase from the $8.6 million of derivative instrument expense recorded in the year ended December 31, 2009.

For the year ended December 31, 2009, Delcath had a net loss of $22.1 million, which is $15.2 million, or 221.3%, more than the net loss from continuing operations for the same period in 2008. This increase was primarily due to a $5.5 million increase in operating costs and a $9.7 million increase in derivative instrument expense, which is a non-cash expense. The increase in operating costs resulted from an acceleration of clinical trial expenses and the building of the management team. The mark-to-market adjustment of the warrant valuation for our warrants issued in 2007 and 2009 resulted in the recording of $8.6 million in derivative instrument expense for the year ended December 31, 2009; a $9.7 million increase from the $1.1 million of derivative instrument income recorded in the year ended December 31, 2008.

General and Administrative Expenses

For the year ended December 31, 2010, Delcath incurred $13.2 million in expenses related to its general and administrative operations. This is a 238.5%, or $9.3 million, increase compared to the same period in 2009. The Company has continued its progress in transitioning from a development stage company focused solely on research and development activities to a commercial enterprise with staff dedicated to future commercialization of the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with these commercialization efforts. A significant portion of this increase is related to the expansion of our Marketing and Sales, Finance, and Manufacturing departments resulting in increasing compensation and related overhead expenses.

For the year ended December 31, 2009, Delcath incurred $3.9 million in expenses related to general and administrative operations. This is a 45.1% increase from the same period in 2008, when the Company incurred $2.7 million in general and administrative expenses. A significant portion of the increase was related to satisfaction of the Company's obligations under a separation agreement with its former President and Chief Executive Officer and the retention of a new President and Chief Executive Officer, as well as the related recruitment and payroll expenses for the expansion of the management team throughout the second half of 2009.

Research and Development Expenses

For the year ended December 31, 2010, research and development costs increased by 83.3%, from $9.6 million for the year ended December 31, 2009 to $17.6 million for the year ended December 31, 2010, an $8.0 million increase. The Company's recent hiring has contributed to a marked increase in research and development expenses. The facility in Queensbury is now operational and Delcath has expanded both our Research and Development and Regulatory and Quality Assurance departments. Additionally, Delcath has focused substantial efforts on completing submissions for FDA approval and CE marking of the Delcath chemosaturation system.

For the year ended December 31, 2009, research and development costs increased by 79.2%, from $5.4 million for the year ended December 31, 2008 to $9.6 million for the year ended December 31, 2009, a $4.3 million increase. The addition of several centers and the increased rate of enrollment in connection with our Phase III clinical trial led to a significant increase in treatments performed and all related expenses in 2009 as compared to 2008.

Interest Income

Interest income shown is from our money market account, treasury bills and investment in various certificates of deposit. For the year ended December 31, 2010, the Company had interest income of $10,698, as compared to interest income of $73,833 for the same period in 2009. This decrease is due to the overall market conditions which continue to yield a lower percentage of return on our investments. The Company will continue to invest conservatively with a focus on preservation of capital and daily liquidity.

For the year ended December 31, 2009, the Company had interest income of $73,833, as compared to interest income of $299,956 for the same period in 2008. This decrease was due to our reduced cash position throughout much of 2009 as Delcath continued to direct funds towards the completion of the Phase III trial, as well as the overall market conditions which yielded a lower percentage of return on investments.

Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. The notes to financial statements included in Item 8 contain a summary of the significant accounting policies and methods used in the preparation of our financial statements. Delcath is still in the development stage and has no revenues, trade receivables, inventories, or significant

fixed or intangible assets, and therefore have very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the Delcath chemosaturation system as well as our research and development activities, the cost of which is required to be charged to expense as incurred. This further limits our choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which our financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying The Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 740, management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that we will realize the benefits of our deferred tax assets. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, FASB ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair

value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Delcath may be exposed to market risk through changes in market interest rates that could affect the value of our investments. However, the Company's marketable securities consist of short-term and/or variable rate instruments and, therefore, a change in interest rates would not have a material impact on the fair value of our investment portfolio or related income.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the 2009 Warrants) in a subscription agreement with a single investor. The Company received gross proceeds of $2,999,999, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2,190,979 to the 2009 Warrants, resulting in net proceeds of $467,559. The fair value of the 2009 Warrants on June 15, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the 2009 Warrants (June 2014). The 2009 Warrants are currently exercisable at $3.60 per share with 1,043,478 shares outstanding at December 31, 2010 and have a five-year term.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the 2007 Warrants) in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at $3.44 per share with 1,469,456 warrants outstanding at December 31, 2010.

The $2,190,979 in proceeds allocated to the 2009 Warrants and the $4,269,000 in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the twelve month period ended December 31, 2010, the Company recorded pre-tax derivative instrument expense of $15,951,367. The resulting derivative instrument liabilities totaled $18,005,014 at December 31, 2010. Management expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to stockholders' equity. The fair value of the Warrants at December 31, 2010 was determined by using the Black-Scholes model assuming a risk free interest rate of 1.25% for the 2009 Warrants and 0.20% for the 2007 Warrants, volatility of 86.23% for the 2009 Warrants and 81.45% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

Item 8. Financial Statements and Supplementary Data

Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Delcath Systems, Inc.

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage company), as of December 31, 2010, and the related statements of operations, stockholders' equity, and cash flows for the year then ended December 31, 2010, and for the period from August 5, 1988 (inception) through December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of December 31, 2009, for each of the two years in the period then ended, and for the period from August 5, 1988 (inception) through December 31, 2009 were audited by other auditors whose report dated February 24, 2010, expressed an unqualified opinion on those statements. The financial statements for the period August 5, 1988 (inception) through December 31, 2009 include a net loss of $22,056,592. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period August 5, 1988 (inception) through December 31, 2010, insofar as it relates to amounts for prior periods through December 31, 2009, is based solely on the report of other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. at December 31, 2010, and the results of its operations and its cash flows for the year then ended and the period from August 5, 1988 (inception) through December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Delcath Systems, Inc. internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Metro Park, NJ
March 8, 2011

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders of Delcath Systems, Inc.

We have audited the accompanying balance sheet of Delcath Systems, Inc. ("Company") as of December 31, 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2009 and cumulative from inception (August 5, 1988) to December 31, 2009. We also have audited the Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Delcath Systems Inc.'s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. as of December 31, 2009, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2009 and cumulative from inception (August 5, 1988) to December

31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, Delcath Systems Inc. maintained in all material respects effective internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ CCR LLP

Glastonbury, CT
February 24, 2010

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Balance Sheets as of December 31, 2010 and 2009

	December 31, 2010	December 31, 2009
Assets:		
Current assets		
Cash and cash equivalents	$ 45,621,453	$ 35,486,319
Investments – Certificates of deposit	1,492,000	–
Prepaid expenses and other assets	1,784,276	799,416
Total current assets	48,897,729	36,285,735
Property, plant and equipment		
Furniture and fixtures	669,296	36,800
Computers and equipment	548,586	78,063
Leasehold improvements	939,518	431,425
	2,157,400	546,288
Less: accumulated depreciation	(477,420)	(24,982)
Property, plant and equipment, net	1,679,980	521,306
Total assets	$ 50,577,709	$ 36,807,041
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 610,457	$ 753,958
Accrued expenses	2,581,853	1,087,522
Warrant liability	18,005,014	11,207,214
Total current liabilities	21,197,324	13,048,694
Deferred revenue	300,000	–
Commitments and contingencies (Note 5)	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2010 and 2009	–	–
Common stock, $.01 par value; 70,000,000 shares authorized; 43,028,146 and 36,223,097 shares issued and 42,932,460 and 36,194,997 outstanding at December 31, 2010 and December 31, 2009, respectively	430,281	362,231
Additional paid-in capital	144,782,807	92,835,174
Deficit accumulated during the development stage	(116,055,400)	(69,371,755)
Treasury stock, at cost; 28,100 shares at December 31, 2010 and December 31, 2009	(51,103)	(51,103)
Accumulated other comprehensive loss	(26,200)	(16,200)
Total stockholders' equity	29,080,385	23,758,347
Total liabilities and stockholders' equity	$ 50,577,709	$ 36,807,041

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Operations
for the Years Ended December 31, 2010, 2009, and 2008, and
Cumulative from Inception (August 5, 1988) to December 31, 2010

	Year ended December 31,			Cumulative from inception (August 5, 1988) To December 31, 2010
	2010	2009	2008	
Costs and expenses				
General and administrative expenses	$ 13,187,278	$ 3,898,705	$ 2,687,688	$ 39,865,082
Research and development costs	17,555,698	9,637,050	5,378,335	56,590,164
Total costs and expenses	30,742,976	13,535,755	8,066,023	96,455,246
Operating loss	(30,742,976)	(13,535,755)	(8,066,023)	(96,455,246)
Derivative instrument (expense) income	(15,951,367)	(8,567,917)	1,103,682	(20,698,602)
Interest income	10,698	73,833	299,956	2,871,279
Other expense	—	(26,753)	(202,500)	(102,753)
Interest expense	—	—	—	(171,473)
Net loss	$ (46,683,645)	$ (22,056,592)	$ (6,864,885)	$ (114,556,795)
Common share data:				
Basic and diluted loss per share	$ (1.20)	$ (0.82)	$ (0.27)	
Weighted average number of basic and diluted common shares outstanding	38,991,481	27,072,556	25,300,703	

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
Cumulative from Inception (August 5, 1988) to December 31, 2010

	Common stock $.01 par value						Preferred Stock $0.01 Par Value		
	Issued		In Treasury		Outstanding				
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	Additional Paid-in capital
Shares issued in connection with the formation of the Company as of August 22, 1988	621,089	$6,211	-	$-	621,089	$6,211	$-	$-	$(5,211)
Sale of Class A preferred stock, August 22, 1988	-	-	-	-	-	-	2,000,000	20,000	480,000
Shares returned due to relevant technology milestones not being fully achieved, March 8, 1990	-	-	(414,059)	(4,141)	(414,059)	(4,141)	-	-	4,141
Sale of stock, October 2, 1990	-	-	17,252	173	17,252	173	-	-	24,827
Sale of stock (common stock at $7.39 per share and Class B preferred stock at $2.55 per share), January 23,	-	-	46,522	465	46,522	465	416,675	4,167	1,401,690

1991									
Sale of stock, August 30, 1991	-	-	1,353	14	1,353	14	-	-	9,987
Sale of stock, December 31, 1992	-	-	103,515	1,035	103,515	1,035	-	-	1,013,969
Sale of stock (including 10,318 warrants, each to purchase one share of common stock at $10.87), July 15, 1994	-	-	103,239	1,032	103,239	1,032	-	-	1,120,968
Sale of stock, December 19, 1996	-	-	39,512	395	39,512	395	-	-	999,605
Shares issued (including 78,438 warrants each to purchase one share of common stock at $10.87) in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984	156,879	1,569	-	-	1,703,395
Sale of stock, December 31, 1997	53,483	535	-	-	53,483	535	-	-	774,465
Exercise of stock options	13,802	138	3,450	35	17,252	173	-	-	30,827
Shares issued as compensation for consulting	2,345	23	828	8	3,173	31	-	-	34,454

services valued at $10.87 per share based on a 1996 agreement									
Shares issued in connection with exercise of warrants	21,568	216	-	-	21,568	216	-	-	234,182
Sale of stock, January 16, 1998	34,505	345	-	-	34,505	345	-	-	499,655
Sale of stock, September 24, 1998	3,450	35	-	-	3,450	35	-	-	56,965
Shares returned as a settlement of a dispute with a former director at $1.45 per share, the price originally paid, April 17, 1998	(3,450)	(35)	-	-	(3,450)	(35)	-	-	(4,965)
Exercise of stock options	8,626	86	-	-	8,626	86	-	-	67,414
Sale of stock (including 5,218 warrants each to purchase one share of common stock at $14.87), June 30, 1999	46,987	470	-	-	46,987	470	-	-	775,722
Shares issued in connection with exercise of warrants	2,300	23	-	-	2,300	23	-	-	24,975

Sale of stock, April 14, 2000	230,873	2,309	-	-	230,873	2,309	-	-	499,516
Dividends paid on preferred stock	690,910	6,909	-	-	690,910	6,909	-	-	992,161
Conversion of preferred stock	833,873	8,339	-	-	833,873	8,339	(2,416,675)	(24,167)	15,828
Sale of stock (including 1,200,000 warrants each to purchase one share of common stock at $6.60), October 19, 2000	1,200,000	12,000	-	-	1,200,000	12,000	-	-	5,359,468

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
Cumulative from Inception (August 5, 1988) to December 31, 2010

	Common stock $.01 par value								
	Issued		In Treasury		Outstanding				
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	Additional Paid-in capital	Deficit Accumulated During Development Stage	To
Shares issued as compensation for stock sale	85,000	850	-	-	85,000	850	(850)	-	-
1,720 stock options (including 1,720 warrants each to purchase one share of common stock at $6.00), issued as compensation	-	-	-	-	-	-	3,800	-	3,800
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	-	-	(36)	(1)	1	-	-
Stock warrants (150,000 at $7.00 and 150,000 at $6.60) issued as compensation	-	-	-	-	-	-	198,000	-	198,0
Sale of stock on April 3,	243,181	2,432	-	-	243,181	2,432	265,068	-	267,5

2002									
Repurchases of stock, November and December 2002			(28,100)	(51,103)	(28,100)	(51,103)	-	-	(51,1
Amortization since inception of compensatory stock options	-	-	-	-	-	-	3,760,951	-	3,760
Forfeiture since inception of stock options	-	-	-	-	-	-	(1,240,780)	-	(1,24
Sale of stock (including 3,895,155 warrants to purchase one share of common stock at $0.775) on May 20, 2003 including underwriter's exercise of over allotment option	3,895,155	38,952	-	-	3,895,155	38,952	1,453,696	-	1,492
Proceeds from sale of unit option, 2003	-	-	-	-	-	-	68	-	68
Exercise of warrants, 2003	1,730,580	17,305	-	-	1,730,580	17,305	1,273,895	-	1,291
Sale of stock, 2004	2,793,975	27,940	-	-	2,793,975	27,940	5,622,690	-	5,650
Exercise of Warrants, 2004	20,265	203	-	-	20,265	203	26,547	-	26,75
Stock options issued as compensation,	-	-	-	-	-	-	5,222	-	5,222

2004									
Exercise of warrants, 2005	4,841,843	48,419	-	-	4,841,843	48,419	7,637,183	-	7,878
Exercise of stock options, 2005	659,000	6,590	-	-	659,000	6,590	569,180	-	575,7
Stock options issued as compensation, 2005	-	-	-	-	-	-	8,270	-	8,270
Sale of stock, November, 2005	753,013	7,530	-	-	753,013	7,530	2,302,471	-	2,310
Shares issued as compensation, 2005	36,925	369	-	-	36,925	369	103,056	-	103,4
Deficit accumulated from inception to December 31, 2005	-	-	-	-	-	-	-	(24,336,562)	(24,3
Balance at December 31, 2005	18,877,753	$188,778	(28,100)	$(51,103)	18,849,653	$137,675	$38,295,388	$(25,835,167)	$12,59
Vesting of stock options, 2006	-	-	-	-	-	-	446,000	-	446,0
Stock options issued as compensation, 2006	-	-	-	-	-	-	505,282	-	505,2
Exercise of warrants, 2006	1,606,928	$16,069	-	-	1,606,928	$16,069	4,877,586	-	4,893
Exercise of stock options, 2006	104,182	1,042	-	-	104,182	1,042	295,024	-	296,0
Shares issued in connection	100,000	1,000	-	-	100,000	1,000	305,000	-	306,0

with settlement of Consent Solicitation lawsuit, 2006									
Net loss, 2006	-	-	-	-	-	-		(10,951,605)	(10,9
Balance at December 31, 2006	20,688,863	$206,889	(28,100)	$(51,103)	20,660,763	$155,786	$44,724,280	$(36,786,772)	$8,093

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
Cumulative from Inception (August 5, 1988) to December 31, 2010

	Common Stock $0.01 Par Value Issued and Outstanding		In Treasury					
	# of Shares	Amount	# of Shares	Amount	Additional Paid-in Capital	Deficit Accumulated During Development Stage	Accumulated Other Comprehensive Loss	Total
Exercise of stock options, 2007	715,413	7,154	-	-	1,793,029	-	-	1,800,183
Shares issued as compensation, 2007	50,000	500	-	-	210,500	-	-	211,000
Sale of stock (including 1,916,554 warrants each to purchase one share of common stock at $4.53), 2007	3,833,108	38,331	-	-	8,995,936	-	-	9,034,267
Compensation expense for issuance of stock options, 2007	-	-	-	-	953,610	-	-	953,610
Net loss, 2007	-	-	-	-	-	(3,663,506)	-	(3,663,506)
Balance at December 31, 2007	25,287,384	$252,874	(28,100)	$(51,103)	$56,677,355	$(40,450,278)	$-	$16,428,848
Cashless exercise of stock options, 2008	970	10	-	-	1,940	-	-	1,950

Shares issued as compensation, 2008	95,000	950	-	-	205,950	-	-	206,900
Compensation expense for restricted stock, 2008	-	-	-	-	80,666	-	-	80,666
Compensation expense for issuance of stock options, 2008	-	-	-	-	377,596	-	-	377,596
Comprehensive loss:								
Net loss	-	-	-	-	-	(6,864,885)	-	(6,864,885)
Change in unrealized loss on investments, 2008	-	-	-	-	-	-	(24,200)	(24,200)
Total comprehensive loss:	-	-	-	-	-	-	-	(6,889,085)
Balance at December 31, 2008	25,383,354	$253,834	(28,100)	$(51,103)	$57,343,507	$(47,315,163)	$(24,200)	$10,206,875
Compensation expense for restricted stock, 2009	91,666	916	-	-	735,500	-	-	736,416
Compensation expense for issuance of stock options, 2009	-	-	-	-	1,578,673	-	-	1,578,673
Sale of stock (including 1,043,478 warrants to purchase one share of	869,565	8,696	-	-	467,559	-	-	476,255

common stock at $3.99), 2009								
Exercise of warrants	103,512	1,035	-	-	355,049	-	-	356,084
Sale of stock, net of expenses, November 2009	9,775,000	97,750	-	-	32,354,886	-	-	32,452,636
Comprehensive loss:								
Net loss	-	-	-	-	-	(22,056,592)	-	(22,056,592)
Change in unrealized loss on investments	-	-	-	-	-	-	8,000	8,000
Total comprehensive loss:	-	-	-	-	-	-	-	(22,048,592)
Balance at December 31, 2009	36,223,097	$362,231	(28,100)	$(51,103)	$92,835,174	$(69,371,755)	$(16,200)	$23,758,347
Compensation expense for restricted stock, 2010	414,042	4,140	-	-	1,671,113	-	-	1,675,253
Compensation expense for issuance of stock options, 2010		-	-	-	3,839,320	-	-	3,839,320
Exercise of warrants and options, common stock surrendered upon restricted stock vesting	1,206,007	12,060	-	-	3,830,071	-	-	3,842,131
Fair value of warrants reclassified	-	-	-	-	9,153,567	-	-	9,153,567

from liability to additional paid-in capital upon exercise								
Sale of stock, net of expenses, August 2010	5,185,000	51,850	-	-	33,453,562	-	-	33,505,412
Comprehensive loss:								
Net loss	-	-	-	-	-	(46,683,645)	-	(46,683,645)
Change in unrealized loss on investments	-	-	-	-	-	-	(10,000)	(10,000)
Total comprehensive loss:	-	-	-	-	-	-	-	(46,693,645)
Balance at December 31, 2010	43,028,146	$430,281	(28,100)	$(51,103)	$144,782,807	$(116,055,400)	$(26,200)	$29,080,385

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Cash Flows
for the Years Ended December 31, 2010, 2009, and 2008 and
Cumulative from Inception (August 5, 1988) to December 31, 2010

	Year ended December 31,			Cumulative from inception (August 5, 1988) to December 31,
	2010	2009	2008	2010
Cash flows from operating activities:				
Net loss	$ (46,683,645)	$ (22,056,592)	$ (6,864,885)	$ (114,556,795)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock option compensation expense	3,839,320	1,578,673	379,546	10,778,259
Restricted stock and warrant compensation expense	1,675,253	736,416	287,566	3,555,947
Depreciation expense	472,291	7,981	5,861	532,034
Amortization of organization costs	—	—	—	42,165
Loss on disposal of equipment	6,730	3,442	—	10,172
Derivative liability fair value adjustment	15,951,367	8,567,917	(1,103,682)	20,698,602
Non-cash interest income	(3,831)	—	—	(11,735)
Changes in assets and liabilities:				
Increase in prepaid expenses and other assets	(991,029)	(438,070)	(5,894)	(1,760,445)
Increase in accounts payable and accrued expenses	1,350,830	1,137,991	578,211	3,192,310
Deferred revenue	300,000	—	—	300,000
Net cash used in operating activities	(24,082,714)	(10,462,242)	(6,723,277)	(77,219,486)
Cash flows from investing activities:				
Purchase of equipment, furniture and fixtures	(1,637,695)	(515,440)	(8,313)	(2,222,387)
Proceeds from sale of equipment	—	200	—	200
Purchase of short-term investments	(3,235,000)	—	(200,710)	(44,646,452)
Purchase of marketable equity securities	—	—	(46,200)	(46,200)
Proceeds from maturities of short-term investments	1,743,000	4,048,614	9,878,700	43,162,356
Organization costs	—	—	—	(42,165)
Net cash (used in) provided by investing activities	(3,129,695)	3,533,374	9,623,477	(3,794,648)
Cash flows from financing activities:				
Net proceeds from sale of stock and exercise of stock options and warrants	37,347,543	35,475,954	—	125,481,261
Repurchases of common stock	—	—	—	(51,103)
Dividends paid on preferred stock	—	—	—	(499,535)

Proceeds from short-term borrowings	—	—	—	1,704,964
Net cash provided by financing activities	37,347,543	35,475,954	—	126,635,587
Increase in cash and cash equivalents	10,135,134	28,547,086	2,900,200	45,621,453
Cash and cash equivalents at beginning of period	35,486,319	6,939,233	7,886,937	—
Cash and cash equivalents at end of period	$ 45,621,453	$ 35,486,319	$ 10,787,137	$ 45,621,453
Supplemental cash flow information:				
Cash paid for interest	$ —	$ —	$ —	$ 171,473
Supplemental non-cash activities:				
Cashless exercise of stock options and shares surrendered upon restricted stock vesting	$ 700,478	$ —	$ 1,950	$ 1,244,594
Conversion of debt to common stock	$ —	$ —	$ —	$ 1,704,964
Common stock issued for preferred stock dividends	$ —	$ —	$ —	$ 999,070
Conversion of preferred stock to common stock	$ —	$ —	$ —	$ 24,167
Common stock issued as compensation for stock sale	$ —	$ —	$ —	$ 510,000
Fair value of warrants issued	$ —	$ 2,190,979	$ —	$ 6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$ 9,153,567	$ —	$ —	$ 9,153,567

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Financial Statements
for the Years Ending December 31, 2010, 2009 and 2008

(1) Description of Business and Summary of Significant Accounting Policies

Description of Business
Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Since its inception, the Company has directed its research efforts towards the development and clinical study of the Delcath chemosaturation system.

The Company's initial focus is on cancers in the liver. Currently, the Delcath chemosaturation system is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver while limiting the systemic exposure of this agent. The Company believes that the Delcath chemosaturation system is a platform technology that 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.

The Company has incurred losses since inception and has a deficit accumulated during the development stage of $116.1 million as of December 31, 2010. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations through 2011, but anticipates that additional working capital may be required to continue operations. There can be no assurance that such working capital will be available on acceptable terms, if at all. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

Basis of Financial Statement Presentation
The accounting and financial reporting policies of the Company conform to accounting principles generally accepted in the United States of America (GAAP). The preparation of financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, income taxes and research and development costs. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Property, Plant and Equipment
Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements of $939,518 at December 31, 2010 will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. Depreciation expense for the years ended December 31, 2010, 2009 and 2008 was $472,291, $7,981, and $5,861, respectively. Since inception, the Company

has incurred depreciation expense of $532,034. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the FASB ASC 740 "Income Taxes." Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled.

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services and FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in

accordance with the provisions of FASB ASC 718. Under the provisions of FASB ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company has expensed its share-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath's common stock at the date of the grant. The Company estimates the fair value of stock options using a Black-Scholes valuation model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath's stock over the option's expected term, the risk-free interest rate over the option's expected term, and Delcath's expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with FASB ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2010 and 2009, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

On January 1, 2008, the Company adopted FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. FASB ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

FASB ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, FASB ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair

value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Net Loss per Common Share

For the years ended December 31, 2010, 2009 and 2008 potential common shares from the exercise of options and warrants and the vesting of restricted stock were excluded from the computation of diluted earnings per share (EPS) because their effects would be antidilutive. In addition, common stock purchase rights issuable only in the event that a non-affiliated person or group acquires 20% of the Company's then outstanding common stock have been excluded from the EPS computation.

Research and Development Costs

Research and development costs include the costs of materials, personnel, outside services and applicable indirect costs incurred in development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

General and Administrative Costs
General and administrative costs include salaries and related expenses for the Company's executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Cash Equivalents and Concentrations of Credit Risk
The Company considers highly liquid debt instruments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Investments
Management determines the appropriate classification of securities at the time of purchase and reevaluates such classification as of each balance sheet date. The Company's securities are classified as either available-for-sale or held-to-maturity. Investments classified as held-to-maturity are stated at amortized cost. Investments classified as available-for-sale are stated at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity.

Deferred Revenue Recognition
Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. This agreement is discussed further in Note 6. The Company will amortize deferred revenue over the expected obligation period of the agreement once this amount is reasonably determinable.

Recently Adopted Accounting Pronouncements
In April 2010, the FASB issued Accounting Standard Update 2010-17, "Revenue Recognition – Milestone Method", a standard that provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for certain research and development transactions. Under this new standard, a company can recognize as revenue consideration that is contingent upon achievement of a milestone in the period in which it is achieved, if the milestone meets all criteria to be considered substantive. The adoption of this update did not have a material effect on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standard Update No. 2009-13 "Multiple Deliverable Revenue Arrangements", an amendment to the accounting standards related to the accounting for revenue derived from arrangements with multiple deliverables including how the arrangement consideration is allocated among delivered and undelivered items under the arrangement. Among the amendments, this standard eliminates the use of the residual method for allocating arrangement consideration and requires an entity to allocate the overall consideration to each deliverable based on an estimated selling price of each individual deliverable in the arrangement in the absence of having vendor-specific objective evidence or other third party evidence of fair value of the undelivered items. This standard also provides further guidance on how to determine a separate unit of accounting in a multiple-deliverable revenue arrangement and expands the disclosure requirements about the judgments made in applying the estimated selling price method and how those judgments affect the timing or amount of revenue recognition. Adoption of this standard did not have a material impact on our consolidated financial statements.

(2) Investments

The Company invests the majority of its cash in money market funds and certificates of deposit. The money market funds are accounted for based on the guidance for fair value measurements and are discussed further in Note 6. The

Company's certificates of deposit are accounted for based on the guidance for investments, which requires securities to be categorized as either trading, available-for-sale or held-to-maturity. The certificates of deposit are classified as held-to-maturity and, as such, are carried at amortized cost. As of December 31, 2010, the Company held certificates of deposit with original maturities of nine to twelve months.

The Company also holds shares of Aethlon Medical which are valued at $20,000 and are classified as an available-for-sale security in Prepaid expenses and other assets. The change in value is recorded in Accumulated other comprehensive loss on the Balance Sheets.

(3) Stockholders' Equity

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

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to 2007 Warrants (see below). The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at $3.44 per share with 1,469,456 warrants outstanding at December 31, 2010. The shares were issued pursuant to an effective registration statement on Form S-3.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of $2,999,999, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2,190,979 to the 2009 Warrants (see below), resulting in net proceeds of $476,255. The fair value of the 2009 Warrants on June 15, 2009 was determined using the Black-Scholes model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the warrants (June 2014). The 2009 Warrants are currently exercisable at $3.60 per share with 1,043,478 warrants outstanding at December 31, 2010 and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

The $2,190,979 in proceeds allocated to the 2009 Warrants and the $4,269,000 in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the twelve month period ended December 31, 2010, the Company recorded pre-tax derivative instrument expense of $15,951,367. The resulting derivative instrument liabilities totaled $18,005,014 at December 31, 2010. Management expects that the Warrants will either be exercised or expire worthless, at which point the then existing derivative instrument liabilities will be credited to stockholders' equity. The fair value of the Warrants at December 31, 2010 was determined by using the Black-Scholes model

assuming a risk free interest rate of 1.25% for the 2009 Warrants and 0.20% for the 2007 Warrants, volatility of 86.23% for the 2009 Warrants and 81.45% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

In August 2010, the Company completed the sale of 5,185,000 shares of its common stock pursuant to an underwriting agreement. The Company received gross proceeds of $35.0 million, with net cash proceeds after related expenses from this transaction of approximately $33.5 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-165677).

Common Stock Repurchases

Pursuant to a stock repurchase plan approved in 2002 by the Company's board of directors, the Company repurchased 28,100 shares of common stock for $51,103 during 2002. The Company had been authorized by the board of directors to purchase up to seven percent of its then outstanding common stock (290,289).

Stock Option Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000, and 4,200,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Compensation and Stock Option Committee of the board of directors which determines the individuals to whom awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

During 2004 and 2009, respectively, the 2004 and 2009 Stock Incentive Plans became effective. Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for 2010, 2009, and 2008 is as follows:

	Number of Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2007	1,140,000	$ 1.88–7.14	$ 4.54	3.96
Granted	525,000	1.23–3.45	1.76	
Expired	(190,000)	1.88–7.14	5.54	
Exercised	(15,000)	1.88	1.88	
Outstanding at December 31, 2008	1,460,000	$ 1.23–6.18	$ 3.44	3.68
Granted	1,885,000	1.24-6.09	3.94	
Expired	—			
Exercised	—			
Outstanding at December 31, 2009	3,345,000	$ 1.23–6.18	$ 3.72	6.58
Granted	700,650	5.28-15.54	9.81	
Expired	(120,000)	2.78-3.59	3.25	
Forfeited	(25,000)	4.12-6.18	4.81	
Exercised	(140,000)	1.43-6.18	3.52	
Outstanding at December 31, 2010	3,760,650	$ 1.23-15.54	$ 4.88	6.65
Exercisable at December 31, 2010	2,398,334		$ 4.03	5.31

The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option valuation model with the following assumptions for option grants during the years ended December 31, 2010, 2009 and 2008:

	Year Ended December 31,		
	2010	2009	2008
Weighted average risk-free interest rate	2.54 %	2.44 %	1.97 %
Weighted average expected volatility	73.80 %	74.58 %	70.72 %
Expected volatility	72.16% - 75.4 %	73.12% - 86.0 %	60.3% - 74.0 %
Dividend yield	0.00 %	0.00 %	0.00 %
Weighted average expected option term (in years)	5.87	5.32	2.60

Weighted average grant date fair value	$ 6.30	$ 2.61	$ 0.68

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life of the stock options on the grant date. The expected holding period was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under FASB ASC 718. This method of determining the expected holding period was utilized because the Company does not have sufficient historical experience from which to estimate the period.

A summary of the Company's non-vested options to purchase shares as of December 31, 2010 and changes during the twelve months ended December 31, 2010 is presented below:

	Non-Vested Options	
	Number of Options	Weighted Average Fair Value
Non-vested at January 1, 2010	1,516,916	$ 4.09
Granted	599,400	9.38
Vested	(729,000)	4.12
Forfeited	(25,000)	4.81
Non-vested at December 31, 2010	1,362,316	$ 6.39

Compensation expense recognized relating to stock options granted to employees totaled $3,647,348, $1,578,673, and $377,596 in 2010, 2009, and 2008, respectively. Since inception, the Company has recognized $10,778,259 in expense related to stock option compensation. In 2010, $2,458,377 was charged to general and administrative expenses, while $1,188,972 was charged to research and development expenses. In 2009, $684,619 was charged to general and administrative expenses, while $894,054 was charged to research and development expenses. In 2008, $198,831 was charged to general and administrative expenses, while $178,765 was charged to research and development expenses. Additional compensation expense of $3,539,356, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 2.06 years.

The aggregate intrinsic value of options outstanding at December 31, 2010 is $19.4 million. The aggregate intrinsic value of options exercisable at December 31, 2010 is $15.0 million. The aggregate intrinsic value represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price of $9.80 as of December 31, 2010, which would have been received by the option holders had those option holders exercised their options as of that date.

Total compensation expense for non-employee stock option grants totaled $191,972 in 2010.

A summary of the Company's restricted stock activity as of December 31, 2010 and changes during the twelve months ended December 31, 2010 is presented below:

	Restricted Stock Activity	
	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at January 1, 2010	307,910	$ 5.23

Granted	56,132	11.16
Vested	(296,452)	6.02
Forfeited	—	
Non-vested at December 31, 2010	67,590	$ 6.71

Compensation expense recognized relating to restricted stock granted to employees totaled $1,656,904, $736,416, and $287,566 in 2010, 2009, and 2008, respectively. Since inception, the Company has recognized $3,555,947 in expense related

to restricted stock and warrant compensation. In 2010, $842,824 was charged to general and administrative expenses, while $814,080 was charged to research and development expenses. In 2009, $162,999 was charged to general and administrative expenses, while $573,417 was charged to research and development expenses. In 2008, $152,850 was charged to general and administrative expenses, while $134,717 was charged to research and development expenses. Additional compensation expense of $301,107, relating to the unvested portion of restricted stock granted, is expected to be recognized over a remaining average period of 1.21 years.

Total compensation expense for non-employee restricted stock totaled $18,349 in 2010.

Warrants
A summary of warrant activity is as follows:

	The Plans			
	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2007	2,480,587	$ 1.02–4.53	$ 4.27	4.13
Issued	–			
Exercised	–			
Expired	(16,500)	1.02–1.28	1.15	
Outstanding at December 31, 2008	2,464,087	$ 3.01–4.53	$ 4.30	3.15
Issued	1,650,760	3.44–3.60	3.54	
Exercised	(103,512)	3.44	3.44	
Expired	(265,151)	3.01	3.01	
Outstanding at December 31, 2009	3,746,184	$ 3.44–3.91	$ 3.52	3.08
Issued	–			
Exercised	(1,159,000)	3.44–3.91	3.52	
Expired	(74,250)	3.91	3.91	
Outstanding at December 31, 2010	2,512,934	$ 3.44-3.60	$ 3.51	2.70

(4) Income Taxes

The provision for income taxes differs from the amount computed by applying the statutory rate as follows:

	Year Ended December 31,		
	2010	2009	2008
Income taxes using U.S. federal statutory rate	$ (15,872,439)	$ (7,643,253)	$ (2,334,061)
State income taxes, net of federal benefit	(4,276,370)	(674,624)	(410,495)
Valuation allowance	15,040,948	5,671,082	3,226,441
Derivative charge	5,423,465	2,913,092	(375,252)
Research and development credits	(519,128)	(345,404)	(211,208)

Other	203,523	79,107	104,575
	$ –	$ –	$ –

Significant components of the Company's deferred tax assets are as follows:

	2010	2009
Deferred tax assets:		
Employee compensation accruals	$ 3,345,000	$ 1,507,000
Accrued liabilities	231,000	–
Research tax credits	1,076,000	557,000
Other	14,000	–
Net operating losses	29,868,000	17,417,000
Total deferred tax assets	34,534,000	19,481,000
Deferred tax liability:		
Total deferred tax liabilities	–	–
Valuation allowance	34,534,000	19,481,000
Net deferred tax assets	$ –	$ –

As of December 31, 2010 and December 31, 2009, the Company had net operating loss carryforwards for federal income tax purposes of approximately $80.0 million and $54.2 million, respectively. A portion of the federal amount, $11.2 million, is subject to an annual limitation of approximately $123,000 as a result of a change in the Company's ownership through May 2003, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitation, approximately $72.3 million is available to offset future federal taxable income which expires through 2030. As of December 31, 2010 and December 31, 2009, the Company had net operating loss carryforwards for state income tax purposes of approximately $120.6 million and $73.8 million, respectively, which expire through 2030.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company's valuation allowance increased by approximately $15.0 million, $5.9 million, $3.2 million and $1.8 million in 2010, 2009, 2008, and 2007, respectively.

The Company has a tax benefit of approximately $927,000 related to the exercise of non qualified stock options. Pursuant to FASB ASC 718, the benefit will be recognized and recorded to additional paid in capital when the benefit is realized through the reduction of taxes payable.

The Company complies with the provisions of FASB ASC 740 in accounting for its uncertain tax positions. ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service or any states in connection with income taxes. The periods from December 31, 2004 to December 31, 2010 remain open to examination by the U.S. Internal Revenue Service and state authorities.

Delcath recognizes interest accrued related to unrecognized tax benefits and penalties, if incurred, as a component of income tax expense.

(5) Commitments

Operating Leases
In February 2010, the Company entered into an agreement to lease (Initial Lease) 8,629 square feet of office space in New York, New York with an option to expand an additional 8,629 square feet. The term of the Initial Lease began in March,

2010 and provides for total annual base rental payments of $457,337 during years 1-3 and the first half of year 4 of the Initial Lease term, and of $491,853 during the second half of year 4 and years 5-7 of the Lease term. The Initial Lease also requires the Company to pay customary building operating expenses and a pro-rata share of real estate taxes.

In September 2010, the Company exercised its option right under the Initial Lease and entered into an agreement to lease (Lease Modification) an additional 8,629 square feet of office space in New York, New York. The term of the Lease Modification began in January 2011 and will expire in November 2020. In addition, the Lease Modification extends the term of the Initial Lease to November 2020. The Lease Modification provides for total annual base rent of $504,078 for years 1-5 of the Lease Modification term and of $547,533 for years 6-11 of the Lease Modification term. In addition, the Lease Modification provides for total base rent on the space leased under the Initial Lease of $543,627 for the extended term of November 2017 – November 2020.

In September 2009, the Company entered into an agreement to lease 10,320 square feet located at 566 Queensbury Avenue, Queensbury, NY (the "Facility") for a three year period with an option to purchase. The Facility houses a portion of the Company's research and manufacturing operations. The term of the lease commenced on September 1, 2009. The lease provides for annual base rent of $51,600, as well as the payment of customary building expenses and real estate taxes. The Company has an option to purchase the Facility upon delivery of written notice to the Landlord at least 120 days prior to expiration of the lease term. The purchase price for the Facility is $425,000 if the Company acquires the Facility by September 1, 2011, and $440,000 if the Company acquires the Facility by September 1, 2012.

In October 2010, the Company entered into an agreement of lease for the lease of 8,000 square feet located at 2 Country Club Road, Queensbury, NY for a two year period with an option to extend the lease for an additional two years. The location houses a portion of the Company's research and manufacturing operations. The term of the lease commenced on November 12, 2012. The lease provides for annual base rent of $96,000, as well as the payment of customary building operating expenses and real estate taxes.

Future minimum lease payments under all operating leases at December 31, 2010 are as follows:

Year Ended December 31:		
2011	$	1,109,016
2012		1,079,815
2013		967,168
2014		995,931
2015		1,006,795
	$	5,161,600

Rent expense totaled approximately $528,243, $221,000, and $221,000, for the years ended December 31, 2010, 2009, and 2008, respectively.

Cooperative Research and Development Agreement

The Company's five year Cooperative Research and Development Agreement (CRADA) for the development of the Delcath chemosaturation system with the National Cancer Institute (NCI) expired on December 14, 2006 and was extended for an additional five years to December 14, 2011. The principal goal of the CRADA is to continue the development of a novel form of regional cancer therapy by designing clinical protocols utilizing the Delcath chemosaturation system to regionally deliver chemotherapeutics to patients with unresectable malignancies confined to an organ or region of the body. Under the five year extension, Delcath will pay $1,000,000 per year to the NCI for clinical support. These funds are payable in quarterly amounts of $250,000 and will be used for material support of the

CRADA (including equipment, supplies, travel, and other related CRADA support), as well as for support of existing or new scientific or clinical staff to be hired by NCI who are to perform work under the CRADA. The Company incurred $1,000,000 per year in expenses related to this agreement for each of the years ended December 31, 2010, 2009, and 2008.

Letters of Credit

Under the terms of the lease agreement for office space in New York City, the Company is required to maintain a letter of credit in the amount of $881,297. The letter of credit expires on February 1, 2012 if not renewed by the Company.

(6) Research and Distribution Agreement

On February 9, 2010, the Company entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd. (the Research and Distribution Agreement). The Research and Distribution Agreement grants Chi-Fu the exclusive right to promote, market, sell and distribute the Delcath chemosaturation system in Taiwan for hepatic malignancies and infectious disease upon Taiwan Food and Drug Administration (TFDA) approval, and for any other TFDA approved indications for treatment using the Delcath chemosaturation system (collectively, the Field of Use). The Research and Distribution Agreement also grants Chi-Fu the right to extend its exclusive distribution rights to Singapore, subject to the satisfaction of certain conditions.

Pursuant to the Research and Distribution Agreement, Chi-Fu will plan, fund and manage clinical studies of the Delcath chemosaturation system in the Field of Use with initial focus on the treatment of hepatic malignancies at not less than two and up to four sites in Taiwan, and will promptly file for TFDA approval of the Delcath chemosaturation system for as many indications of use as possible, promptly following Delcath's receipt of U.S. Food and Drug Administration (FDA) approval of the Delcath chemosaturation system. Chi-Fu's exclusive right to market, sell and distribute the Delcath chemosaturation system in Taiwan in the Field of Use will begin on the date TFDA approval of the Delcath chemosaturation system is granted and will continue for the term of the Research and Distribution Agreement. Beginning on the first day of the month in which TFDA approval is obtained, Chi-Fu is obligated to purchase a minimum number of Delcath systems annually during the term of the Research and Distribution Agreement; with such minimum purchase requirements to increase annually over the remaining term of the Research and Distribution Agreement. The Research and Distribution Agreement requires Chi-Fu to pay Delcath $1 million in milestone payments, comprised of $300,000 paid upon execution of the Research and Distribution Agreement; $200,000 paid within thirty days of Delcath's receipt of a CE Mark for the Delcath chemosaturation system, and $500,000 within thirty days of Delcath's receipt of FDA approval for the Delcath chemosaturation system.

The term of the Research and Distribution Agreement commenced on February 9, 2010 and will continue for five (5) years from the first day of the month in which TFDA approval is obtained, following which the Research and Distribution Agreement will automatically renew for an additional five (5) years provided Chi-Fu has met all of its obligations under the Research and Distribution Agreement, including its minimum purchase requirements.

(7) Assets and Liabilities Measured at Fair Value

Derivative Financial Instruments
As disclosed in Note 3, the Company allocated proceeds to the warrants issued in connection with a private placement and recent public offering that were classified as liabilities and accounted for as a derivative instrument in accordance with FASB ASC 815. The valuation of the warrants is determined using the Black-Scholes model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the Black Scholes model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in FASB ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (820-10). The riskless rate of return is a Level 2 input as defined in 820-10, while the historical volatility is a Level 3 input as defined in FASB ASC 820. Since the lowest level input is a

Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

Marketable Equity Securities

The Company owns 100,000 shares of common stock of Aethlon Medical, Inc (AEMD) a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. At December 31, 2010, the valuation of such stock is determined utilizing the current quoted market price of AEMD due to the selling restrictions as stated in the agreement to purchase these shares having lapsed during the year. The Company has determined that the inputs associated with the fair value determination are readily observable and as a result the instrument was classified within Level 1 of the fair-value hierarchy.

Money Market Funds and Treasury Bills

Cash and cash equivalents includes a money market account valued at approximately $45.4 million.

The Company has determined that the inputs associated with the fair value determination are based on quoted prices (unadjusted) and as a result the investments are classified within Level 1 of the fair value hierarchy.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2010, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis at December 31, 2010

	Level 1	Level 2	Level 3	Balance at December 31, 2010
Assets				