DELCATH SYSTEMS INC
Form 10-K
February 26, 2010

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, 2009

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.)
600 Fifth Avenue, 23rd Floor, New York, NY	10020
(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 $3.58 per share, was $84,383,897 as of June 30, 2009.

At February 25, 2010, the registrant had outstanding 36,311,090 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2010 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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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains "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 "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable termi 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 Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. 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 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; and
- submission and timing of applications for regulatory approval.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements contained in this Annual Report on Form 10-K, which speak only as of the date of this report. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

Item 1. Business

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "Delcath", "Delcath Systems","we", "our", and "us" refers to Delcath Systems, Inc., a Delaware corporation, incorporated in Augus 1988. Our corporate offices are located at 600 Fifth Avenue, 23rd Floor, New York, New York 10020. Our telephone number is (212) 489-2100.

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

General Development of Business

Overview

We are a development stage company that has developed an innovative system designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. Since our inception we have focused our efforts on the development of a single product, the Delcath Percutaneous Hepatic Perfusion System, or (the Delcath PHP System), which provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System is minimally invasive and repeatable. We believe that the Delcath PHP System is a platform technology

that may have broader applicability to other organs and body regions. In our initial application, the Delcath PHP System isolates the liver from the patient's general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers. The Phase III and Phase II clinical trials are subject to the terms and conditions of a Cooperative Research and Development Agreement, the CRADA, between us and the National Cancer Institute, or NCI. The Delcath PHP System is not currently approved by the U.S. Food and Drug Administration (FDA), and it cannot be marketed in the United States without prior FDA approval.

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

We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we enrolled all of the 92 patients called for under a Special Protocol Assessment, or SPA, granted by the FDA. We expect to submit our application to the FDA by mid-2010 for the treatment of hepatic tumors secondary to melanoma with the Delcath PHP System. The FDA regulates the Delcath PHP System as a combination product: the combination of a medical device and a drug. Before we can market the Delcath PHP System, we must obtain FDA approval of the drug and device under a Section 505(b)(2) new drug application, or NDA.

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

Since our inception, we have raised approximately $88.1 million in aggregate funds (net of expenses).We have used approximately $39.0 million of those funds for research and development costs associated with development and testing of the Delcath PHP System, and have cumulative net losses of approximately $67.9 million. Since 2006 we have accelerated our investment in and expanded the scope of our clinical trials.

In 2009, we re-focused our management team and appointed a new Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. For the years ended December 31, 2009, 2008 and 2007, we invested $9.6 million, $5.4 million, and $4.2 million respectively on research and development activities.

Strategy

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

- Complete our Phase III clinical trial and obtain FDA approval for use of the Delcath PHP System in combination with melphalan to treat metastatic melanoma in the liver. As of October 2009, we enrolled all 92 patients called for under the SPA granted by the FDA. Our highest priority is completing the related data preparation, statistical analysis and filing of necessary regulatory documents associated with obtaining FDA approval for the commercial sale of the Delcath PHP System in the United States for the treatment of melanoma that has spread to the liver.
- Establish strategic alliances to introduce the Delcath PHP System into non-U.S. markets. Our strategy addresses non-U.S. markets, including Asia and Europe, that have both a high incidence of liver disease and the public or private means to provide and pay for treatment with our technology. We have begun the process of seeking the CE mark approval to market the Delcath PHP System in the European Economic Area, or EEA, and hope to receive approval in the second half of 2010. We also are establishing strategic relationships with domestic and foreign firms that have an established presence or experience in certain foreign markets.
- Obtain approval to market the Delcath PHP System in the United States for the treatment of other cancers in addition to metastatic melanoma in the liver. We are currently conducting a multi-arm Phase II trial to evaluate the Delcath PHP System for the treatment of other cancers of the liver, such as primary liver cancer, tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, as well as melanomas in the liver that received certain prior regional treatment with melphalan.
- Develop United States sales force and marketing team. We intend to market the Delcath PHP System in the United States directly by focusing our initial marketing efforts on the over fifty NCI-designated cancer centers in the United States, beginning with the hospitals participating in our Phase III clinical trial. We plan to focus

our efforts on (i) surgeons who administer the Delcath PHP System; (ii) oncologists who have primary responsibility for cancer patients; and (iii) interventional radiologists who are physicians specialized in working with catheter-based systems.

- Test the Delcath PHP System with drugs other than melphalan for the treatment of cancers of the liver. In addition to testing melphalan, we have tested the drugs doxorubicin and 5-FU with the Delcath PHP System in humans and we intend to evaluate other drug candidates for use with the Delcath PHP System to treat other tumors in the liver. We are currently developing filters with affinity to agents used in treatments for these areas.
- Investigate using anti-viral drugs with the Delcath PHP System. We believe that our technology may be compatible with other compounds, including anti-virals, to treat other diseases of the liver such as hepatitis.
- Explore other regional therapy applications for the Delcath PHP System. We are evaluating the treatment of other organs and regions of the body that may be well suited for the use of our technology. Other organs or body regions that may be evaluated for compatibility with our technology include kidneys, pancreas and lungs.

The Cancer Treatment Market

Industry Background

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

The Liver Cancer Market

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

According to "Cancer Facts & Figures 2009," the five-year survival rate for liver cancer patients is approximately 12%, compared to 66% for all forms of cancer combined. Metastatic, or secondary, liver cancer is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. This growth often continues even after removal of the primary cancer in another part of the body has occurred. Given the primary biological function of the liver, including filtering toxins from the blood, it is not uncommon for metastases to settle in the liver and in many cases, patients die not as a result of their primary cancer, but from the tumors that metastasize in their liver. We believe that in the United States, metastatic liver cancer may be more prevalent than primary liver cancer. Our most advanced trial is a study for patients with metastatic ocular and cutaneous melanoma in the liver. The incidence of cutaneous melanoma is approximately 55,100 cases per year, with 15% to 20% of cases metastasizing in the liver.

The incidence of ocular melanoma is approximately 4,000 cases per year, with up to 90% of cases metastasizing to the liver. The preferred method to treat liver cancer, once detected, is surgical removal of the diseased portion of the liver. Frequently, symptoms of liver cancer do not appear until the liver tumors have spread broadly within the liver, making surgical resection impractical. As a consequence, less than 10% of primary and metastatic liver tumors can be surgically removed. A significant number of patients who are surgically resected for primary or metastatic liver cancer will also experience a recurrence of their disease.

Current Liver Cancer Treatments

Limited effective treatment options are currently available for liver cancer, and they are generally associated with significant side effects and even death. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgically isolated perfusion and liver transplant.

Resection

Surgical resection is considered the "gold standard" treatment option for liver tumors. However, approximately 90% of liver tumors are unresectable, which means they do not qualify for surgical removal. For the patients who qualify for surgery, the procedure is highly invasive and can result in significant complications. Additionally, recurrence of tumors is common, and in that event, surgery typically cannot be repeated because the patient cannot survive removal

of additional liver tissue or the new tumor sites are too widespread. Resection is a limited solution for patients with liver cancer because it is not an option for many patients and it is not a repeatable procedure.

Chemoembolization

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

Chemotherapy

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

Radiation Therapy

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

Thermal Therapies

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

Treatment with the Delcath PHP System

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

The most advanced application for which the Delcath PHP System is being evaluated is treatment of metastatic melanoma in the liver. The Delcath PHP System isolates the liver from the patient's general circulatory system, allowing for the administration of high and concentrated doses of chemotherapeutic drugs directly to the isolated liver. The Delcath PHP System then captures and diverts the flow of blood exiting the liver, which contains high doses of chemotherapeutic agents. The blood passes through filters located outside of the body that remove the majority of these high doses of chemotherapy from the blood before it is reintroduced to the patient's general circulatory system. The chemotherapeutic agent remaining in the bloodstream after filtration is a fraction of the infused drug, resulting in manageable toxicities.

Based on our clinical trial data, we believe that the Delcath PHP System allows for higher doses of the chemotherapy agent to be delivered to the liver than what would otherwise be possible through conventional intravenous chemotherapy or chemoembolization. As a result, we believe the treatment kills a greater number of cancer cells and may lead to better clinical outcomes. In some cases, delivery of drugs with the Delcath PHP System could potentially allow for the use of previously unavailable therapies. Chemotherapy could also be administered through the Delcath PHP System after resection with the objective of destroying micro metastases in the liver that may remain undetected, thus preventing or delaying any recurrence of tumor growth.

The side effects caused by the drug we use in our current clinical trials, melphalan, are similar to the side effects associated with delivery of the drug by traditional methods. However, because the Delcath PHP System filters out the high doses of the drug, it controls the exposure of healthy tissue and organs to the effects of chemotherapeutic agents.

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

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

- Filtration circuit outside the body—a blood tubing circuit containing disposable components used with a non-disposable blood pump which push the isolated blood through the Delcath PHP System's filters and deliver the filtered blood back to the patient.
- Filters—two hemofiltration filters used to remove most of the chemotherapy agent from the isolated blood coming out of the liver before the blood is returned to the patient's general circulatory system.
- Return catheter—a thin-walled blood sheath used to deliver the filtered blood from the filtration circuit outside the body back into the patient's general circulatory system.
- Series of introducers and related accessories to properly place the catheters – The Delcath PHP System involves a series of three catheter insertions, each of which is made through standard interventional techniques. In most cases to date, general anesthesia has been used. An infusion catheter is positioned in the artery that supplies blood to the liver. A second catheter—the Delcath double balloon catheter—is positioned in the inferior vena cava, a major vessel leading back to the heart. A third catheter is placed in the patient's jugular vein to return the filtered blood to the patient. The balloons on the double balloon catheter are then inflated. This procedure prevents the normal flow of blood from the liver to the heart through the inferior vena cava because the inferior vena cava has been blocked. After isolation of the liver is confirmed, a chemotherapy agent is infused into the liver through the infusion catheter. The drug-laden blood is prevented from flowing to the heart and instead is collected as it exits the liver through the double balloon catheter. Blood flows through the double balloon catheter out of the body where it is pumped through two filters to remove most of the chemotherapy agent. The filtered blood is returned via the return catheter to the patient's general circulatory system through the jugular vein.

In our clinical trials, chemotherapy infusion takes place over a period of thirty minutes. Filtration occurs during infusion and for an additional thirty minutes after the infusion is completed. After the sixty-minute filtration period is complete, the catheters are removed and manual pressure is maintained on the catheter puncture sites. The entire procedure takes approximately two to three hours to administer. During our clinical trials, patients typically remain in the hospital overnight for observation after undergoing treatment with the Delcath PHP System. An advantage of the Delcath PHP System is that the procedure is repeatable and in the current clinical trials, a patient may undergo six treatments at approximately four to six week intervals. A new disposable Delcath PHP System kit is used for each treatment.

Our Clinical Trials

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

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

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

In the trial, patients are randomly assigned to receive treatments with melphalan using the Delcath PHP System, or to a control group providing best alternative care. Patients assigned to the Delcath PHP System may receive up to six cycles of treatment at approximately four to six week intervals. Patients randomized to the non-Delcath PHP System arm are permitted to cross-over into the Delcath arm at documentation of hepatic disease progression. To date, a majority of the control patients have been crossed over to the treatment arm. Secondary objectives of the study are to determine the response rate, safety and tolerability of treatments using the Delcath PHP System in patients with cutaneous and ocular melanoma metastatic to the liver and the patterns of recurrence of patients treated with the Delcath PHP System for metastatic melanoma, and to determine the overall survival in patients with hepatic metastases following treatment with standard treatments and after treatment with the Delcath PHP System.

The FDA has granted the Delcath PHP System with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. We have submitted our protocol for the Delcath PHP System with melphalan to the FDA pursuant to a Special Protocol Assessment, or SPA. An SPA is an evaluation by the FDA of our protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. We have received a letter from the FDA stating that the SPA we submitted to the FDA was acceptable. We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we had enrolled all of the 92 patients called for under the SPA. We expect to submit our application to the FDA by mid-2010 for the treatment of hepatic tumors secondary to melanoma with the Delcath PHP System.

Phase II Trial

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

Phase I Trials

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

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

Results. Our Phase I clinical trials demonstrated that the Delcath PHP System is capable of delivering ten times more of the chemotherapy agent to the treated region, and the effective concentration at the tumor site is nearly 100 times greater than the traditional delivery methods. The Delcath PHP System also controls systemic toxicities by isolating the circulation of the organ or region from the patient’s circulatory system. This allows a higher dose of chemotherapeutic agent to be used than the dose that would be safe to deliver intravenously. Our Phase I clinical trials, demonstrated that the Delcath PHP System is capable of extracting approximately 85% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.

Strategic Alliances

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

Sales and Marketing

We plan to seek one or more corporate partners to market products outside the United States. We believe distribution or corporate partnering arrangements internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target. We intend to market the Delcath PHP System in the United States ourselves focusing our initial marketing efforts on the over fifty NCI-designated cancer centers in the United States, beginning with the hospitals participating in the Phase III clinical trial. We plan to focus our efforts on three distinct groups of medical specialists in these comprehensive cancer centers:

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

Subsequent to December 31, 2009, we entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd., a Taiwanese company, to conduct clinical studies of the Delcath PHP System and, upon obtaining approval of the Taiwan Food and Drug Administration (TFDA), to market, sell and distribute the Delcath PHP System in Taiwan and possibly Singapore for TFDA indications of use.

Third-Party Reimbursement

Because the Delcath PHP 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, we will seek to have third-party payers, such as Medicare, Medicaid and private health insurance plans, reimburse the cost of the Delcath PHP System and the associated procedures. In the United States, third-party payors consist of government programs, such as Medicare, private health insurance plans, managed care organizations and other similar programs. Three factors are key to the reimbursement of any product:

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

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

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

Manufacturing

We plan to assemble, sterilize and package the Delcath PHP System kit at our facility in Queensbury, New York. We currently utilize contract manufacturers to manufacture the components of the Delcath PHP System. The Delcath PHP System kit components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. The catheters and catheter accessories contained within the Delcath PHP System kit are being manufactured by AngioDynamics, Inc. and the OEM division of B. Braun Medical, Inc. Medtronic USA, Inc. manufactures the components of the blood filtration circuit, including the medical tubing through which a patient's blood flows and various connectors, as well as the blood filtration pump accessories. Bipore Medical Devices, Inc. manufactures the filters used with the Delcath PHP System. Delcath is working with Bipore and other filter manufacturers to develop other specialized filters for use within the Delcath PHP System. Our suppliers' manufacturing facilities are ISO 13485 certified and operate under the auspices of FDA. Subsequent to December 31, 2009, we entered into a written supply agreement with B.Braun Medical, Inc. to supply us with double balloon catheters and double balloon catheter accessory packs. We intend to pursue written agreements with other suppliers to manufacture the components of the Delcath PHP System for commercial sale.

Competition

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

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

Government Regulation

The Delcath PHP System is regulated by the FDA as a combination product consisting of a device and a drug. The manufacture and sale of medical devices and drugs are subject to extensive governmental regulation in the United States and in other countries. The Delcath PHP System is regulated in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. As such, FDA approval of the Delcath PHP System is required before any commercial distribution may commence.

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

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

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

When 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". 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 we provide information to the FDA on any deaths or serious adverse events that may have been caused or contributed to by the use of the marketed product and product malfunctions that would likely cause or contribute to a death or serious injury if the malfunction were to recur.

Drugs

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

Orphan Drug Regulation

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

Foreign Regulation

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

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

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

Intellectual Property and Other Rights

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

Patent Titles	Patent No.	Expiration Date
Cancer treatment and catheter for use in treatment	U.S. #5,411,479	May 2, 2012
Apparatus and method for isolated pelvic perfusion	U.S. #5,817,046	July 14, 2017
Balloon catheter with occluded segment bypass	U.S. #5,893,841	August 30, 2016
Catheter with slideable balloon	U.S. #5,919,163	July 14, 2017
Cancer treatment method	U.S. #6,186,146	January 13, 2017
Catheter flow and lateral movement controller	U.S. #5,897,533	September 2, 2017
Method for treating glandular diseases and malignancies	U.S. #7,022,097	May 9, 2023

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

In certain circumstances, U.S. patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. We intend to seek extension for one of our patents after FDA approval. We also rely on trade secrets and proprietary technological experience. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. These agreements may not provide meaningful protection of our proprietary technologies or other intellectual property if unauthorized use or disclosure occurs or if they do not adequately protect against disclosure of material proprietary information.

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

Employees and Facilities

In 2009, we re-focused our management team and appointed a new Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. As of December 31, 2009, we had 17 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Our corporate offices currently occupy 3,400 square feet of office space at 600 Fifth Avenue, New York, N.Y. under a sublease that expires in July 2010. We have outgrown this space due to the recent growth of the Company's management team. On February 5, 2010, we entered into a lease for approximately 8,629 square feet of office space at 810 Seventh Avenue, New York, NY. We expect to relocate our corporate offices to this location.

On September 3, 2009, we announced that we signed a three-year lease with an option to buy a 10,320 square foot facility in Queensbury, New York, where we plan to locate assembling, sterilization and packaging of the Delcath PHP System. We anticipate hiring approximately 20 people at this facility by the end of fiscal 2010 to establish manufacturing, distribution, and research and development capabilities. Since major medical device companies have located their catheter operations in this area for decades, the local labor force is well acquainted with the manufacturing requirements that Delcath will face as it progresses toward full-scale production of the Delcath PHP System.

Available Information

We maintain a website at www.delcath.com. We make 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 we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or the SEC. We are 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 we are not successful in developing and obtaining FDA approval of the drug/device combination product, or if we are unable to market and sell the product, we will not generate operating revenue or become profitable.
The Delcath PHP System, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs for the treatment of a variety of diseases, is our only product, and our entire focus has been on developing, commercializing, and obtaining regulatory approvals of this product. If the Delcath PHP System fails as a commercial product, we have no other products to sell.

Continuing losses may exhaust our capital resources.
We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. We expect to incur significant and increasing losses while generating minimal revenues over the next few years. From our inception on August 5, 1988 through December 31, 2009, we have incurred cumulative net losses of approximately $67.9 million. For the years ended December 31, 2009, 2008 and 2007 we incurred net losses of approximately $22.1 million, $6.9 million, and $3.7 million, respectively. To date, we have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2007, June 2009 and November 2009. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development and commercialization of the Delcath PHP System.

If we cannot raise the additional capital that may be required to commercialize the Delcath PHP System, our potential to generate future revenues will be significantly limited even if we receive FDA approval, and if we cannot raise additional capital generally, our business operations may be harmed.
The Delcath PHP System is regulated by the FDA as a combination product. Before we can obtain approval to sell our product commercially in the United States we will need approval from the FDA. We will also need approval to market our products in foreign markets. We do not know if additional financings will be available when needed, or if they are available, that they will be available on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to complete our trials, obtain regulatory approvals or sell the Delcath PHP System commercially.

Our liquidity and capital requirements will depend on numerous factors, including: our research and product development programs, including clinical studies; the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing of product commercialization activities, including marketing arrangements overseas; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the impact of competing technological and market

developments. We do not know if additional financing will be available if needed, or if it is available, if it will be available on acceptable terms. Insufficient funds may require us to curtail or stop our research and development activities.

Risks Related to FDA and Foreign Regulatory Approval

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

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

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

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

Obtaining FDA approvals could be delayed.

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

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

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

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

- the FDA may put our clinical trials on hold;
- the results of those trials could be negative;
- additional serious adverse events in the clinical trials could occur;
- we could experience difficulty in obtaining a supplier of melphalan in a timely manner;
- we could experience manufacturing difficulties; and
- other regulators or institutional review boards may not authorize, or may delay, suspend or terminate the clinical trial program due to safety concerns.

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

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

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

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

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

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

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

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

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

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

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

We intend to enter into one or more strategic alliances to further address markets outside the United States and to fund the development of additional indications or for use with additional chemotherapy agents within the United States. We 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 PHP System or any other product or the generation of revenue.

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

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

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

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

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

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

The loss of key personnel could adversely affect our business.

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

Risk Related to Patents, Trade Secrets and Proprietary Rights

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

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical combination products to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. If this type of litigation is successful, a third party may be able to obtain an injunction prohibiting us from offering our product. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath PHP System or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Certain of our U.S. and foreign patents have already expired and other U.S. patents relating to the Delcath PHP System will expire beginning in 2012 through 2023.

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

Risk Related to Products Liability

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

Clinical trials, manufacturing and product sales may expose us to liability claims from the use of the Delcath PHP System. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in the clinical trials and result in the

loss of physician endorsement. A successful products liability claim or recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry 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;
- FDA delay or disapproval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the Delcath PHP System;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;
- a challenge to one of our patents, either in court or via administrative proceedings in the U.S. Patent and Trademark Office; and
- conditions generally affecting the healthcare and cancer treatment industries; and the success of our operating strategy.

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

The market price of our common stock has historically been volatile. During the three years ended December 31, 2009, 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 $6.19 (during the fiscal quarter ended December 31, 2009) to a low of $0.87 (during the fiscal quarter ended December 31, 2008). During the twelve months ended December 31, 2009, the range of the high and low last reported sales prices of our common stock have ranged from a high of $6.19 (during the fiscal quarter ended December 31, 2009) to a low of $1.18 (during the fiscal quarter ended March 31, 2009). Sales of substantial amounts of common stock, or the perception that such sales could occur, could have an adverse effect on prevailing market prices for our common stock.

Our insiders beneficially own a significant portion of our stock.
Our insiders beneficially own a significant portion of our stock. As of December 31, 2009, our executive officers, directors and affiliated persons beneficially owned approximately 12.3% of our common stock. As a result, our executive officers, directors and affiliated persons will have significant influence to:

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

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.

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

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

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

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.
If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the 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. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

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

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate offices currently occupy 3,400 square feet of office space at 600 Fifth Avenue, New York, N.Y. under a sublease that expires in July 2010. We have outgrown this space due to the recent growth of the Company's management team. On February 5, 2010, we entered into a lease for approximately 8,629 square feet of office space at 810 Seventh Avenue, New York, NY, with an option to expand an additional 8,629 square feet. We expect to relocate our corporate offices to this location.

In addition, we lease a building containing approximately 10,320 square feet of manufacturing, research and development, and office space in Queensbury, New York under a lease agreement that expires on August 31, 2012. We have an option to purchase the building prior to the expiration of the lease term.

We believe 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. Submission of Matters to a Vote of Security Holders.

None.

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 closing prices of our common stock for the fiscal quarters indicated as reported on The NASDAQ Capital Market:

Common Stock Price Range

	Sale Price	
Year ended December 31, 2009	High	Low
First Quarter	$ 1.95	$ 1.18
Second Quarter	3.98	1.78
Third Quarter	5.05	2.81
Fourth Quarter	6.19	4.02

	Sale Price	
Year ended December 31, 2008	High	Low
First Quarter	$ 2.22	$ 1.20
Second Quarter	2.67	1.66
Third Quarter	2.55	1.26
Fourth Quarter	1.54	0.82

On February 25, 2010 there were 81 stockholders of record of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our common stock and we have no intention to do so in the foreseeable future.

Recent Sales of Unregistered Securities

We did not sell any equity securities that were not registered under the Securities Act of 1933, as amended, in the fourth quarter of 2009.

Performance Graph

The following graph compares the cumulative total stockholder return on our common stock over the five-year period ended December 31, 2009, 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, 2004, 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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	12/04	12/05	12/06	12/07	12/08	12/09
Delcath Systems Inc.	100.00	112.96	122.92	61.46	39.53	169.77
NASDAQ Composite	100.00	101.33	114.01	123.71	73.11	105.61
Hemscott Industry Group 513 - Drug Delivery	100.00	89.57	80.41	86.50	43.35	63.30

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, 2009 and 2008 and for the years ended December 31, 2009, 2008 and 2007 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)	2009	2008	2007	2006	2005
Statement of Operations Data					
Costs and expenses	$ 13,536	$ 8,066	$ 6,913	$ 11,699	$ 3,112
Operating loss	13,536	8,066	6,913	11,699	3,112
Net loss	22,057	6,865	3,664	10,952	2,865
Loss per share	(0.82)	(0.27)	(0.16)	(0.55)	(0.18)

	Year Ended December 31,				
(Dollars in thousands)	2009	2008	2007	2006	2005
Balance Sheet Data					
Current assets	$ 36,286	$ 11,341	$ 18,091	$ 8,760	$ 12,920
Total assets	36,807	11,359	18,106	8,764	12,928
Current liabilities	13,049	1,152	1,677	670	330
Stockholder's equity	23,758	10,207	16,429	8,093	12,598

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.

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

We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we enrolled all of the 92 patients called for under the Special Protocol Assessment, or SPA, granted by the FDA. Until April 2008, the National Cancer Institute, or NCI was the sole participating center in the trial. Since then, we have negotiated and entered into research relationships with eleven centers as part of this trial, bringing the total number of centers to twelve:

2008, 2nd Quarter
University of Maryland Medical Center
St. Luke's Cancer Center
Albany Medical Center
Atlantic Melanoma Center of

Atlantic Health	
University of Texas Medical Branch	
2008, 3rd Quarter	
Swedish Medical Center	
John Wayne Cancer Institute	
Providence Health Systems	
Moffitt Cancer Center	
2008, 4th Quarter	
University of Pittsburgh Medical Center	
2009, 1st Quarter	
Ohio State University Comprehensive Cancer Center	

Either a participating center's Institutional Review Board ("IRB") or the Western Institutional Review Board ("WIRB") has approved our treatment protocol. The WIRB, which provides review services for more than 100 institutions (academic centers, hospitals, networks and in-house biotech research) in all 50 states and internationally, will help accelerate the internal review process at a number of the hospitals currently participating in the study. As of December 31, 2009, we completed enrollment in the Phase III clinical trial. In 2004, we began a multi-arm Phase II clinical trial for the use of the Delcath PHP System with melphalan in the treatment of hepatocellular carcinomas as well as neuroendocrine and adenocarcinoma cancers that have spread to the liver. In 2007, an additional arm was added to the Phase II clinical trial to treat patients with metastatic melanoma that has spread to the liver who have received prior regional treatment with melphalan. Based on promising initial clinical results, we focused our efforts on enrolling patients for the treatment of metastatic neuroendocrine tumors. That arm of the clinical trial has 25 patients enrolled.

The successful development of the Delcath PHP System is highly uncertain, and development costs and timelines can vary significantly and are difficult to accurately predict. Various statutes and regulations also impact the manufacturing, safety, labeling, storage, record keeping and marketing of our system. The lengthy process of completing clinical trials, seeking FDA approval and subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To date, we have not received approval for the sale of our system in any market and, therefore, have not generated any revenues. The Delcath PHP System has not yet been approved by the FDA and may not be marketed in the United States without FDA approval.

Our expenses generally include costs for clinical studies, securing patents, regulatory activities, manufacturing, personnel, rent for our facilities, and general corporate and working capital, including general and administrative expenses. Because we have 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. We cannot be assured that we will obtain FDA approval for our Delcath PHP System, that we will have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for our product.

We expect that the amount of capital required to complete our Phase III clinical trial, prepare the Company's submission to the FDA, and establish a fully operational manufacturing facility in upstate New York will continue to increase over the coming months. We believe that we have sufficient capital for operations through 2010.

We are a development stage company, and since our inception we have raised approximately $88.1 million (net of expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we anticipate that losses will continue over the coming years.

Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we anticipate that losses will continue over the coming year. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including our ongoing Phase II and Phase III clinical trials; the timing and costs of making various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing and effectiveness 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 effect of competing technological and market developments. We continue to move forward aggressively, most notably by reaching full enrollment in our Phase III clinical trial, opening a manufacturing facility, and expanding our management team in anticipation of various regulatory, manufacturing and commercialization efforts. As we seek FDA approval of the Delcath PHP System and get our product to market we expect that both our expenses and capital expenditures will increase significantly.

At December 31, 2009, cash and cash equivalents totaled $35,486,319, as compared to $6,939,233 at December 31, 2008. Approximately $35.1 million and $6.9 million of our funds are currently invested in money markets at December 31, 2009 and 2008, respectively.

During the twelve months ended December 31, 2009, we used $10,462,242 of cash in our operating activities. This amount compares to $6,723,277 used in our operating activities during the comparable twelve month period ended December 31, 2008. The increase of $3,738,965, or 55.6%, is primarily due to the recent additions to our

management team as well as the acceleration of clinical development costs relating to all facets of the Delcath PHP System. We expect that our cash allocated to operating activities will continue to increase significantly as we outfit and fully staff our new facility in upstate New York, and continue to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our operating activities through 2010.

At December 31, 2009, the Company's accumulated deficit was approximately $69.4 million, as compared to $47.3 million at December 31, 2008. Because our business does not generate positive cash flow from operating activities, we will likely need to continue raising additional capital in order to develop our product beyond the current clinical trials or to fund development efforts relating to new products. We anticipate that we could raise additional capital in the event that we find it in our best interest to do so. We anticipate 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 we need it, we 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 those planned 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 June 2009, 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 $60,000,000 of common stock, preferred stock, stock purchase contracts, warrants and debt securities as it deems prudent or necessary to raise capital at a later date. The registration statement became effective on June 23, 2009 (333-159913). The Company used this registration statement for its November 2009 public offering detailed in Note 3 in the footnotes to the 2009 financial statements. Because the maximum aggregate offering price of all securities registered is $60,000,000, 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.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003 along with our registered direct offerings in 2007 and 2009, and our recent public offering in November, 2009. As of December 31, 2009, we had approximately $25,000,000 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 of Form S-3 filed in June 2009 (333-159913). 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 2009 financial statements.

Contractual Obligations, Commercial Commitments and Off-Balance Sheet Arrangements

We are 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 our significant contractual obligations at December 31, 2009 (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	$ 2.0	$ 1.0	$ 1.0	$ -	$ -
Operating Leases	0.3	0.2	.1	-	-

Our five year CRADA for the development of the Delcath PHP 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 PHP System to regionally deliver chemotherapeutics to patients with unresectable malignancies confined to an organ or region of the body. Under the five year extension, we 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.

Our operating lease obligations at December 31, 2009 include: the annual rent under the sublease for our office space at 600 Fifth Avenue, New York, NY ($221,000 per annum), which sublease will expire on July 30, 2010 and the annual rent under the lease for our manufacturing facility in Queensbury, New York ($51,600 per annum), which lease expires on August 31, 2012. See Part I, Item 2, "Properties".

Future Capital Needs; Additional Future Funding

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve consistent profitability. We believe that our capital resources are adequate to fund operations through 2010, but anticipate that prior to commercialization we may require additional working capital 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, 2009; Comparisons of Results of the Years Ended December 31, 2008 and 2007

We have operated at a loss for our entire history. We had a net loss for the twelve months ended December 31, 2009, of $22,056,592, which is $15,191,707, or 221.3%, more than the net loss from continuing operations for the same period in 2008. This increase is primarily due to a $5.47 million increase in operating costs and a $9.67 million increase in derivative instrument expense, which is a non-cash expense. The increase in operating costs is related to an acceleration of clinical trial expenses and the recent additions to the management team. The warrants issued in 2007 and 2009 as part of our sale 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 $8,567,917 in derivative instrument expense for the year ended December 31, 2009; a $9,671,599 increase from the $1,103,682 of derivative instrument income recorded in the year ended December 31, 2008.

We had a net loss for the twelve months ended December 31, 2008, of $6,864,885, which is $3,201,379, or 87.4%, more than the net loss from continuing operations for the same period in 2007. This increase is primarily due to increased research and development costs due to an acceleration of patient enrollment as discussed below. Additionally, the warrants issued in 2007 as part of our sale 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 $1,103,682 in derivative instrument income for the year ended December 31, 2008; a $1,613,318 decrease from the $2,717,000 of derivative instrument income recorded in the year ended December 31, 2007. This fluctuation accounts for approximately fifty percent of the difference in net loss between 2008 and 2007.

General and Administrative Expenses

For the twelve months ended December 31, 2009, we incurred $3,898,705 in expenses related to our general and administrative operations. This is a 45.1% increase from the same period in 2008, when we incurred $2,687,688 in general and administrative expenses. A significant portion of this increase is related to satisfaction of the Company's obligations under a separation agreement with its former President and CEO 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.

General and administrative expenses increased by less than 1% from $2,671,782 during the twelve months ended December 31, 2007, to $2,687,688 for the twelve months ended December 31, 2008. An increase in fees paid to board of director members as well as an increase in insurance related costs during 2008 was offset primarily by a reduction of payroll related expenses charged to general and administrative which accounted for slight increase in the expense during fiscal year 2008.

Research and Development Expenses

For the twelve months ended December 31, 2009, research and development costs increased by 79.2%, from $5,378,335 for the twelve months of 2008 to $9,637,050 for the twelve months ended December 31, 2009, a $4,258,715 increase. The addition of several centers and the increased rate of enrollment in connection with our Phase III clinical trial has led to a significant increase in treatments performed and all related expenses in 2009 as compared to 2008. With full enrollment in the Phase III clinical trial, the Company anticipates spending directed towards the Phase III clinical trial will begin to steady, while expenses related to the Company's preparation for FDA submission and the development of our newly-leased manufacturing facility in upstate New York will begin accelerating.

During the twelve months ended December 31, 2008, we incurred $5,378,335 in research and development costs, which is a 26.8% increase as compared to $4,241,517 of research and development costs we incurred during 2007. This increase is primarily due to the acceleration of enrollment in our Phase III trial. With the addition of several trial sites throughout 2008, we experienced a marked increase in the rate of patient enrollment and treatment which has had a noticeable impact on our research and development expenses.

Interest Income

Interest income shown is from our money market account, treasury bills and investment in various certificates of deposit. For the twelve months 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 is due to our reduced cash position throughout much of 2009 as we continued to direct our funds towards the completion of our Phase III trial, as well as the overall market conditions which continue to yield a lower percentage of return on our investments. Given our increased cash position at the end of 2009, we anticipate an increase in interest income during 2010, but will continue to invest conservatively with a focus on preservation of capital and daily liquidity.

During the twelve months ended December 31, 2008, we had interest income of $299,956, as compared to interest income of $532,793 for the same period in 2007, a 43.7% change. This decrease is primarily due to a reduced cash position in 2008 from that in 2007, as well as the overall market conditions which yielded a lower percentage return on our 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. We are still in the development

stage and have 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, we must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, we devote substantial resources to clinical trials and other research and development activities relating to obtaining FDA and other approvals for the Delcath PHP System, 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.

We consider 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.

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. The adoption of FASB ASC 820 did not have a material effect on the carrying values of the Company's assets.

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

We 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.

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc., ("AEMD") a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of this agreement, the Company purchased 100,000 shares of restricted common stock of AEMD. The Company allocated $46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement and then discounting that value due to certain sale restrictions on the stock being held. In September 2008 the sale restriction on the stock being held lapsed and as a result the fair value of the stock is no longer being discounted. The investment is classified as an available for sale security and had a fair value on December 31, 2009 of $30,000 which included a gross unrealized loss of $16,200, which is included as a component of comprehensive loss.

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 exercisable at $3.60 per share 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 2,420,324 warrants outstanding.

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, 2009, the Company recorded pre-tax derivative instrument expense of $8,567,917. The resulting derivative instrument liabilities totaled $11,207,214 at December 31,2009. 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, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.42% for the 2009 Warrants and 1.55% for the 2007 Warrants, volatility of 72.47% for the 2009 Warrants and 85.58% 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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Delcath Systems, Inc.

We have audited the accompanying balance sheets of Delcath Systems, Inc. ("Company") as of December 31, 2009 and 2008, and the related statements of operations, other comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-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 2008, and the results of its operations and its cash flows for each of the years in the three-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, 2009 and 2008

	December 31, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$35,486,319	$6,939,233
Investments – certificates of deposit	—	3,847,904
Investments - treasury bills	—	200,710
Prepaid expenses and other assets	799,416	353,346
Total current assets	36,285,735	11,341,193
Property, plant and equipment		
Furniture and fixtures	36,800	23,170
Computers and equipment	78,063	21,030
Leasehold improvements	431,425	—
	546,288	44,200
Less: accumulated depreciation	(24,982)	(26,711)
Property, plant and equipment, net	521,306	17,489
Total assets	$36,807,041	$11,358,682
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$1,841,480	$703,489
Derivative instrument liabilities	11,207,214	448,318
Total current liabilities	13,048,694	1,151,807
Commitments and contingencies (Note 5)	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $.01 par value; 70,000,000 shares authorized; 36,223,097 and 25,383,354 shares issued and 36,194,997 and 25,355,254 outstanding at December 31, 2009 and December 31, 2008, respectively	362,231	253,834
Additional paid-in capital	92,835,174	57,343,507
Deficit accumulated during development stage	(69,371,755)	(47,315,163)
Treasury stock, at cost: 28,100 shares at December 31, 2009 and December 31, 2008	(51,103)	(51,103)
Accumulated other comprehensive loss	(16,200)	(24,200)
Total stockholders' equity	23,758,347	10,206,875
Total liabilities and stockholders' equity	$36,807,041	$11,358,682

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Operations
for the Years Ended December 31, 2009, 2008, and 2007, and
Cumulative from Inception (August 5, 1988) to December 31, 2009

	Year ended December 31,			Cumulative from inception (August 5, 1988) To December 31, 2009
	2009	2008	2007	
Costs and expenses				
General and administrative expenses	$3,898,705	$2,687,688	$2,671,782	$26,677,804
Research and development costs	9,637,050	5,378,335	4,241,517	39,034,466
Total costs and expenses	13,535,755	8,066,023	6,913,299	65,712,270
Operating loss	(13,535,755)	(8,066,023)	(6,913,299)	(65,712,270)
Derivative instrument (expense) income	(8,567,917)	1,103,682	2,717,000	(4,747,235)
Interest income	73,833	299,956	532,793	2,860,581
Other expense	(26,753)	(202,500)	—	(102,753)
Interest expense	—	—	—	(171,473)
Net loss	$(22,056,592)	$(6,864,885)	$(3,663,506)	$(67,873,150)
Common share data:				
Basic and diluted loss per share	$(0.82)	$(0.27)	$(0.16)	
Weighted average number of basic and diluted common shares outstanding	27,072,556	25,300,703	22,321,488	

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Other Comprehensive Loss
for the Years Ended December 31, 2009, 2008, and 2007 and Cumulative from Inception (August 5, 1988) to December 31, 2009

	Years Ended December 31,			
	2009	2008	2007	Cumulative
Other comprehensive loss:				
Net loss	$(22,056,592)	$(6,864,885)	$(3,663,506)	$(67,873,150)
Change in unrealized gain (loss) on investments	8,000	(24,200)	—	(16,200)
Other comprehensive loss	$(22,048,592)	$(6,889,085)	$(3,663,506)	$(67,889,350)

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, 2009

ssued	Common stock $.01 par value In Treasury		Outstanding		Preferred Stock $0.01 Par Value				
res Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
$6,211	-	$-	621,089	$6,211	$-	$-	$(5,211)	$-	$1,000
-	-	-	-	-	2,000,000	20,000	480,000	-	500,000
-	(414,059)	(4,141)	(414,059)	(4,141)	-	-	4,141	-	-
-	17,252	173	17,252	173	-	-	24,827	-	25,000
-	46,522	465	46,522	465	416,675	4,167	1,401,690	-	1,406,322
-	1,353	14	1,353	14	-	-	9,987	-	10,001
-	103,515	1,035	103,515	1,035	-	-	1,013,969	-	1,015,004
-	103,239	1,032	103,239	1,032	-	-	1,120,968	-	1,122,000
-	39,512	395	39,512	395	-	-	999,605	-	1,000,000
585	98,388	984	156,879	1,569	-	-	1,703,395	-	1,704,964
535	-	-	53,483	535	-	-	774,465	-	775,000
138	3,450	35	17,252	173	-	-	30,827	-	31,000
23	828	8	3,173	31	-	-	34,454	-	34,485
216	-	-	21,568	216	-	-	234,182	-	234,398
345	-	-	34,505	345	-	-	499,655	-	500,000
35	-	-	3,450	35	-	-	56,965	-	57,000
) (35)	-	-	(3,450)	(35)	-	-	(4,965)	-	(5,000
86	-	-	8,626	86	-	-	67,414	-	67,500
470	-	-	46,987	470	-	-	775,722	-	776,192
23	-	-	2,300	23	-	-	24,975	-	24,998
2,309	-	-	230,873	2,309	-	-	499,516	-	501,825

	6,909	-	-	690,910	6,909	-	-	992,161	(1,498,605)	(499,535
	8,339	-	-	833,873	8,339	(2,416,675)	(24,167)	15,828	-	-
00	12,000	-	-	1,200,000	12,000	-	-	5,359,468	-	5,371,468

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, 2009

	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	Total
s compensation	85,000	850	-	-	85,000	850	(850)	-	-
tions (including each to hare of at $6.00), pensation	-	-	-	-	-	-	3,800	-	3,800
nal common d after year ts	(36)	(1)	-	-	(36)	(1)	1	-	-
(150,000 at 000 at $6.60) pensation	-	-	-	-	-	-	198,000	-	198,000
n April 3, 2002	243,181	2,432	-	-	243,181	2,432	265,068	-	267,500
f stock, December			(28,100)	(51,103)	(28,100)	(51,103)	-	-	(51,103
ince inception ry stock options	-	-	-	-	-	-	3,760,951	-	3,760,951
e inception of	-	-	-	-	-	-	(1,240,780)	-	(1,240,780
ncluding rants to hare of at $0.775) on including xercise of over on	3,895,155	38,952	-	-	3,895,155	38,952	1,453,696	-	1,492,648
sale of unit	-	-	-	-	-	-	68	-	68
rrants, 2003	1,730,580	17,305	-	-	1,730,580	17,305	1,273,895	-	1,291,200
2004	2,793,975	27,940	-	-	2,793,975	27,940	5,622,690	-	5,650,630
arrants, 2004	20,265	203	-	-	20,265	203	26,547	-	26,750
ssued as 2004	-	-	-	-	-	-	5,222	-	5,222
rrants, 2005	4,841,843	48,419	-	-	4,841,843	48,419	7,637,183	-	7,878,484
	659,000	6,590	-	-	659,000	6,590	569,180	-	575,770

ck options,									
ssued as 2005	-	-	-	-	-	-	8,270	-	8,270
November,	753,013	7,530	-	-	753,013	7,530	2,302,471	-	2,310,001
as 2005	36,925	369	-	-	36,925	369	103,056	-	103,425
ulated from ecember 31,	-	-	-	-	-	-	-	(24,336,562)	(24,336,562)
cember 31, 2005	18,877,753	$ 188,778	(28,100)	$ (51,103)	18,849,653	$ 137,675	$ 38,295,388	$ (25,835,167)	$ 12,597,896
ck options, 2006	-	-	-	-	-	-	446,000	-	446,000
ssued as 2006	-	-	-	-	-	-	505,282	-	505,282
rrants, 2006	1,606,928	$ 16,069	-	-	1,606,928	$ 16,069	4,877,586	-	4,893,655
ck options,	104,182	1,042	-	-	104,182	1,042	295,024	-	296,066
n connection t of Consent vsuit, 2006	100,000	1,000	-	-	100,000	1,000	305,000	-	306,000
	-	-	-	-	-	-		(10,951,605)	(10,951,605)
cember 31, 2006	20,688,863	$ 206,889	(28,100)	$ (51,103)	20,660,763	$ 155,786	$ 44,724,280	$ (36,786,772)	$ 8,093,294

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, 2009

	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
Change in unrealized loss on investments, 2008	-	-	-	-	-	-	(24,200)	(24,200)
Net loss, 2008	-	-	-	-	-	(6,864,885)	-	(6,864,885)
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 common stock at $3.99), 2009	869,565	8,696	-	-	467,559	-	-	476,255
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
Change in unrealized loss on investments	-	-	-	-	-	-	8,000	8,000
Net loss	-	-	-	-	-	(22,056,592)	-	(22,056,592)
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

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Cash Flows
for the Years Ended December 31, 2009, 2008, and 2007 and
Cumulative from Inception (August 5, 1988) to December 31, 2009

	Year ended December 31,			Cumulative from inception (August 5, 1988) to December 31, 2009
	2009	2008	2007	
Cash flows from operating activities:				
Net loss	$(22,056,592)	$(6,864,885)	$(3,663,506)	$(67,873,150)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock option compensation expense	1,578,673	379,546	1,404,610	6,938,939
Stock and warrant compensation expense	736,416	287,566	211,000	1,880,694
Depreciation expense	7,981	5,861	4,323	59,743
Amortization of organization costs	—	—	—	42,165
Loss on disposal of equipment	3,442	—	—	3,442
Derivative liability fair value adjustment	8,567,917	(1,103,682)	(2,717,000)	4,747,235
Non-cash interest income	—	—	—	(7,904)
Changes in assets and liabilities:				
Increase in prepaid expenses and other assets	(438,070)	(5,894)	(263,535)	(769,416)
Increase (decrease) in accounts payable and accrued expenses	1,137,991	578,211	(545,089)	1,841,480
Net cash used in operating activities	(10,462,242)	(6,723,277)	(5,569,197)	(53,136,772)
Cash flows from investing activities:				
Purchase of equipment, furniture and fixtures	(515,440)	(8,313)	(15,641)	(584,692)
Proceeds from sale of equipment	200	—	—	200
Purchase of short-term investments	—	(200,710)	(9,878,700)	(41,411,452)
Purchase of marketable equity securities	—	(46,200)	—	(46,200)
Proceeds from maturities of short-term investments	4,048,614	9,878,700	2,408,302	41,419,356
Organization costs	—	—	—	(42,165)
Net cash provided by (used in) investing activities	3,533,374	9,623,477	(7,486,039)	(664,953)
Cash flows from financing activities:				
Net proceeds from sale of stock and exercise of stock options and warrants	35,475,954	—	14,652,450	88,133,718
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	35,475,954	—	14,652,450	89,288,044
Increase in cash and cash equivalents	28,547,086	2,900,200	1,597,214	35,486,319
Cash and cash equivalents at beginning of period	6,939,233	7,886,937	6,289,723	—
Cash and cash equivalents at end of period	$35,486,319	$10,787,137	$7,886,937	$35,486,319
Supplemental cash flow information:				

Cash paid for interest	$—	$—	$—	$171,473
Supplemental non-cash activities:				
Cashless exercise of stock options	$—	$1,950	$451,000	$544,116
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	$—	$4,269,000	$6,459,979

See Accompanying Notes to these Financial Statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Financial Statements
for the Years Ending December 31, 2009, 2008 and 2007

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

(a) Description of Business

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

(b) 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 those statements. 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.

(c) Property, Plant and Equipment

Property, plant and equipment are recorded at cost and are being depreciated on a straight line basis over the estimated useful lives of the assets which range from three to five years. Leasehold improvements of $431,425 at December 31, 2009 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, which is anticipated to be fiscal year 2010. Depreciation expense for the years ended December 31, 2009, 2008 and 2007 was $7,981, $5,861, and $4,323, respectively. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

(d) 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. The Company's income tax returns were prepared on the cash basis of accounting through December 31, 2008. The Company has filed Form 3115, Application for Change in Method of Accounting, to change its tax accounting method from the cash basis to accrual basis for years beginning after December 31, 2008. 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. See Note 4 for additional information.

(e) Stock Option Plan

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. 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 based upon the grant date fair value, estimated in accordance with the provisions of FASB ASC 718. 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 our 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 our stock over the option's expected term, the risk-free interest rate over the option's expected term, and our 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. See Note 3 for additional information.

(f) 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, 2009 and 2008, the Company did not have any derivative instruments that were designated as hedges.

Derivative instrument expense of $8,567,917, derivative instrument income of $1,103,682, and derivative instrument income of $2,717,000 for the years ended December 31, 2009, 2008, and 2007 respectively, reflect a non-cash mark-to-market adjustment for the derivative instrument liability resulting from warrants issued in connection with the private placements completed by the Company in September 2007 and June 2009. See Note 6 for additional information.

(g) 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. The FASB has partially delayed the effective date for one year for certain fair value measurements when those measurements are used for financial statement items that are not measured at fair value on a recurring basis.

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.

(h) Net Loss per Common Share

For the years ended December 31, 2009, 2008 and 2007 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.

(i) 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.

(j) 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.

(k) Investments

The Company accounts for its investments in debt and equity instruments under FASB ASC 320. The Company classified its investments as available-for-sale. Management determines the appropriate classification of such securities at the time of purchase and reevaluates such classification as of each balance sheet date.

In 2009, marketable securities are stated at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity. The Company follows the guidance provided by FASB ASC 320 to assess whether our investments with unrealized loss positions are other than temporarily impaired. Realized gains and losses and declines in value judged to be other than temporary are determined based on the specific identification method. To date, only temporary impairment charges have been recorded. See Note 6 for additional information.

(l) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation.

(m) Recently Adopted Accounting Pronouncements

In January 2009, the Company adopted FASB ASC 815-10-65, which requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The adoption of FASB ASC 815-10-65 did not have a material impact on the financial statements.

In July 2009, the Company adopted FASB ASC 855-10 which requires the Company to evaluate events occurring between the end of the year being reported and the date the financial statements are issued or are available to be issued. The Company evaluated subsequent events after the balance sheet date of December 31, 2009 through February 24, 2010.

In October 2009, the Company adopted FASB ASC 105-10, which establishes the FASB ASC as the source of authoritative principles and standards to be applied in the preparation of financial statements in conformity with GAAP. As FASB ASC is not intended to change or alter existing GAAP, it will not impact our financial statements.

(2) Investments

The Company's investments consist of common stock in Aethlon Medical, Inc., which is included in the prepaid expenses and other assets caption of the Company's balance sheets.

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc., ("AEMD") a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of this agreement, the Company purchased 100,000 shares of restricted common stock of AEMD. The Company allocated $46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement and then discounting that value due to certain sale restrictions on the stock being held. In September 2008, the sale restriction on the stock being held lapsed and as a result the fair value of the stock

is no longer being discounted. The investment is classified as an available for sale security and had a fair value as of December 31, 2009 and 2008 of $30,000 and $22,000, respectively, resulting in a gross unrealized loss of $16,200 and $24,200 as of December 31, 2009 and 2008, respectively, and is included as a component of comprehensive loss.

(3) Stockholders' Equity

(a) 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%.

During 2006, the Company received net proceeds of $4,893,655 upon the exercise of 1,606,928 Common Stock Warrants that resulted in the issuance of 1,606,928 shares of common stock.

The Company received a net amount of $204,900 upon the exercise of 220,000 stock options during 2006. 70,000 options were exercised at a price of $2.78 per share; 10,000 were exercised at a price of $1.03 per share; and a cashless exercise of 70,000 options with an exercise price of $2.78 per share and 70,000 options with an exercise price of $3.59 per share collectively resulting in the issuance of 24,182 shares of common stock.

During 2006, the Company issued 100,000 shares of common stock having a value of $3.06 per share on the date of issuance to Laddcap Value Partners LP as partial reimbursement for its expenses associated with the settlement of a lawsuit relating to its solicitation of written consents from the Company's stockholders.

The Company received a net amount of $1,349,184 upon the exercise of stock options for 617,850 shares of common stock, $0.01 par value per share during 2007. Of those options: (i) 100,000 were exercised at a price of $0.71 per share, (ii) 126,000 were exercised at a price of $1.03 per share, (iii) 20,000 were exercised at a price of $1.32 per share, (iv) 200,000 were exercised at a price of $2.78 per share, (v) 100,000 were exercised at a price of $3.28 per share, and (vi) 71,850 were exercised at a price of $3.31 per share.

During 2007, a cashless exercise of 70,000 options with an exercise price of $2.78 per share, 140,000 options with an exercise price of $3.59 per share, 80,000 options with an exercise price of $3.28 per share, and 60,300 options with an exercise price of $3.31 per share collectively resulted in the issuance of 97,563 shares of common stock.

During 2007, the Company issued 50,000 shares of common stock to its former President and Chief Executive Officer that had an issuance value of $3.95 per share for the 25,000 issued on May 24, 2007 and $4.49 for the 25,000 shares issued on July 2, 2007. The Company recorded compensation expense of $211,000 relating to the stock issuance.

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 2,420,324 warrants outstanding. The shares

were issued pursuant to an effective registration statement on Form S-3.

During 2008, the Company issued 95,000 shares of common stock to senior management and the board of directors at the fair market value of the stock at the date of issuance, resulting in the Company recording compensation expense of $206,900.

In July 2008, the Company granted 200,000 restricted shares of common stock to a member of senior management that was scheduled to vest in equal increments over three years on the anniversary date of the agreement. The Company recorded $80,666 of compensation expense relating to the restricted stock agreement during 2008 and $80,667 of compensation expense during 2009. The unvested portion of this stock grant, 133,334 shares, was forfeited during the fourth quarter of 2009.

In September 2008, a cashless exercise of 15,000 options with an exercise price of $1.88 per share resulted in the issuance of 970 shares of common stock and compensation expense of $1,950.

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 exercisable at $3.60 per share and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (333-143280, as amended by 333-159857).

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, 2009, the Company recorded pre-tax derivative instrument expense of $8,567,917. The resulting derivative instrument liabilities totaled $11,207,214 at December 31,2009. 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, 2009was determined by using the Black-Scholes model assuming a risk free interest rate of 2.42% for the 2009 Warrants and 1.55% for the 2007 Warrants, volatility of 72.47% for the 2009 Warrants and 85.58% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

In November 2009, the Company completed the sale of 9,775,000 shares of its common stock in a public offering pursuant to an underwriting agreement. The Company received gross proceeds of $35,190,000, with net cash proceeds after related expenses from this transaction of approximately $32.5 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-159913).

During 2009, the Company granted 387,910 shares of common stock to management and the board of directors at the fair market value of the stock at the date of grant. Of the total shares granted 25,000 shares vested immediately upon issuance, 50,000 shares vested upon the completion of the capital raise in November 2009 and were issued in January 2010, and the remaining 312,910 shares vest over periods ranging from twelve to thirty-six months. The Company recorded compensation expense of $655,749 during 2009 and will expense the remaining $1,373,718 of compensation expense over the vesting period.

During 2009, the Company issued 103,512 shares of common stock upon the exercise of warrants for total cash proceeds of $356,084.

(b) 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).

(c) Stock Option Plans

The Company established the 2000 Stock Option Plan, the 2001 Stock Option Plan, the 2004 Stock Incentive Plan, and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 300,000, 750,000, 3,000,000, and 2,000,000 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 2000, 2001, 2004 and 2009, respectively, the 2000 and 2001 Stock Option Plans and 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 2009, 2008, and 2007 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2006	1,465,650	$ 0.71–3.59	$ 2.87	3.57
Granted	845,000	1.88–7.14	4.98	
Expired	(202,500)	3.59	3.59	
Exercised	(968,150)	0.71–3.59	2.59	
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

At December 31, 2009, 2008 and 2007, options for 1,828,084, 1,286,666, and 1,023,333, respectively, were exercisable at a weighted average exercise price of $3.42, $3.42, and $4.52, per share, and a weighted average remaining term of 4.21, 2.98, and 2.45 years, respectively. The aggregate intrinsic value of options outstanding and exercisable at December 31, 2009 is $3.4 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 $5.11 as of December 31, 2009, which would have been received by the option holders had those option holders exercised their options as of that date.

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 weighted-average assumptions for option grants during the years ended December 31, 2009, 2008 and 2007:

	Years Ended December 31,		
	2009	2008	2007
Risk-free interest rate	2.44%	1.97%	4.60%
Expected volatility of common stock	74.58%	70.72%	57.56%
Dividend yield	0.00%	0.00%	0.00%
Expected option term (in years)	5.32	2.60	2.58
Grant date fair value	2.61	0.68	1.33

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 718-10-S99. 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, 2009 and changes during the twelve months ended December 31, 2009 is presented below:

	Non-Vested Options	
	Number of Options	Weighted Average Fair Value
Non-vested at January 1, 2009	173,334	$ 1.34
Granted	1,725,000	4.05
Vested	(381,418)	3.67
Forfeited	–	
Non-vested at December 31, 2009	1,516,916	$ 4.09

Total compensation expense recognized relating to stock option grants totaled $1,578,673, $377,596, and $953,610 in 2009, 2008, and 2007, respectively. Additional compensation expense of $3,491,886, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 2.21 years.

(d) 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, 2006	564,033	$ 1.02–3.91	$ 3.41	3.04
Issued	1,916,554	4.53	4.53	
Exercised	–			
Expired	–			
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

(4) Income Taxes

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

	Year Ended December 31,		
	2009	2008	2007
Income taxes using U.S. federal statutory rate	$ (7,643,253)	$ (2,334,061)	$ (1,245,592)
State income taxes, net of federal benefit	(674,624)	(410,495)	(46,582)
Valuation allowance	5,671,082	3,226,441	1,813,480
Derivative charge	2,913,092	(375,252)	(923,780)
Expiration of net operating losses	–	–	207,061
Research and development credits	(345,404)	(211,208)	–
Other	79,107	104,575	195,413
	$ –	$ –	$ –

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

	2009	2008
Deferred tax assets:		
Employee compensation accruals	$ 1,507,000	$ 861,000
Accrual to cash	–	145,000
Research tax credits	557,000	211,000
Net operating losses	17,417,000	12,369,000
Total deferred tax assets	19,481,000	13,586,000
Deferred tax liability:		
Valuation allowance	19,481,000	13,586,000
Net deferred tax assets	$ –	$ –

As of December 31, 2009 and December 31, 2008, the Company had net operating loss carryforwards for federal income tax purposes of approximately $54,693,000 and $42,885,000, respectively. A portion of the federal amount, $11,879,000, 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, $45,222,000 is available to offset future federal taxable income which expires through 2029. As of December 31, 2009 and December 31, 2008, the Company had net operating loss carryforwards for state income tax purposes of approximately $49,008,000 and $35,403,000, respectively, which expire through 2029.

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 $5.9 million, $3.2 million and $1.8 million in 2009, 2008, and 2007, respectively.

The Company has a tax benefit of approximately $373,000 related to the exercise of non qualified stock options. Pursuant to FASB ASC 718, the benefit will be recognized and recorded to APIC when the benefit is realized through the reduction of taxes payable.

The Company complies with the provisions of FASB ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 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 740-10, 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 740-10.

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, 2003 to December 31, 2009 remain open to examination by the U.S. Internal Revenue Service and state authorities.

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

(5) Commitments

(a) Operating Leases

The Company currently occupies office space under a sublease that expires in July 2010. Annual fixed rent during the term of the lease is $221,000 per annum plus a pro-rata share of common area maintenance, property taxes and insurance. Rent expense totaled approximately $221,000, $221,000, and $99,000 for the years ended December 31, 2009, 2008 and 2007, respectively.

On September 1, 2009, the Company entered into a three year lease with option to purchase (the "Lease") with Fitzgerald Brothers Beverages, Inc. (the "Landlord"), for the real property and free standing building thereon, containing approximately 10,320 square feet located at 566 Queensbury Avenue, Queensbury, NY (the "Facility"). The Facility will house the Company's manufacturing operations. The term of the Lease commenced on September

1, 2009. Base rent on the Lease is $51,600 per year, payable in equal monthly installments of $4,300 on the first day of each month. 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 $400,000 if the Company acquires the Facility by September 1, 2010, $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.

(b) Cooperative Research and Development Agreement

The Company's five year Cooperative Research and Development Agreement ("CRADA") for the development of the Delcath PHP 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 PHP 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, in expenses related to this agreement for each of the years ended December 31, 2009, 2008, and 2007.

(c) Letters of Credit

Under the terms of the sublease agreement for office space, the Company is required to maintain a letter of credit in the amount of $165,700. The letter of credit expires on August 9, 2010 if not renewed by the Company.

(6) Assets and Liabilities Measured at Fair Value

(a) 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 820-10-35. 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 our 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 (820-10-35-40). The riskless rate of return is a Level 2 input as defined in 820-10-35-48, while the historical volatility is a Level 3 input as defined in FASB ASC 820-10-55-22. 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.

(b) 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, 2009, 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.

(c) Money Market Funds and Treasury Bills

Cash and cash equivalents includes a money market account valued at approximately $35.1 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, 2009, 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, 2009

	Level 1	Level 2	Level 3	Balance at December 31, 2009
Assets				
Marketable equity securities	$ 30,000	$ —	$ —	$ 30,000
Money market funds	35,115,245	—	—	35,115,245
Liabilities				
Derivative instrument liabilities	$ —	$ —	$ 11,207,214	$ 11,207,214

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	Derivative
Beginning balance	$ 448,318
Total losses included in earnings	8,567,917
Issuance of warrants, June 2009	2,190,979
Ending balance	$ 11,207,214

(7) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2009 and 2008.

	2009 Quarters Ended			
(in thousands except per share amounts)	March 31	June 30	September 30	December 31
Net sales	$—	$—	$ —	$ —
Gross profit	—	—	—	—
Operating loss	(1,936)	(2,442)	(3,733)	(5,425)
Derivative instrument expense	(562)	(3,904)	(3,831)	(271)
Net loss	(2,445)	(6,328)	(7,586)	(5,698)
Basic and diluted loss per share	(0.10)	(0.25)	(0.29)	(0.18)

	2008 Quarters Ended			
(in thousands except per share amounts)	March 31	June 30	September 30	December 31
Net sales	$—	$—	$ —	$ —
Gross profit	—	—	—	—
Operating loss	(1,430)	(1,799)	(2,214)	(2,623)
Derivative instrument income (expense)	198	(671)	1,281	296
Net loss	(1,058)	(2,420)	(878)	(2,509)
Basic and diluted loss per share	(0.04)	(0.10)	(0.03)	(0.10)

(8) Subsequent Events

On February 4, 2010, the Company announced that sufficient events had been reached to allow data analysis to begin on its Phase III clinical trial for the treatment of metastatic melanoma in the liver using the Delcath PHP System.

On February 9, 2010, the Company announced the signing of its first research, distribution, sales and marketing agreement. The agreement grants Chi-Fu Trading Co., Ltd., a Taiwanese company, the exclusive right to conduct clinical studies of the Delcath PHP System and, upon obtaining approval of the Taiwan Food and Drug Administration (TFDA), to market, sell and distribute the Delcath PHP System in Taiwan and possibly Singapore.

On February 9, 2010, the Company announced that it had entered into an agreement for the lease of approximately 8,629 square feet of office space at 810 Seventh Avenue, New York, NY, with the option to expand an additional 8,629 square feet. Delcath's executive offices will be relocated to this new office space.

On February 24, 2010, the Company announced that it had entered into a supply agreement with B. Braun Medical Inc., a Pennsylvania corporation, (the "Supply Agreement"), pursuant to which B. Braun Medical Inc. has agreed to supply Delcath with double balloon catheters and double balloon catheter accessory packs, to sell Delcath certain tooling and related equipment for the manufacturing of such products, and to provide Delcath with certain technical and design assistance. B. Braun Medical Inc. is a current supplier of catheters and catheter accessories to Delcath.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of December 31, 2009 (the end of the period covered by this Annual Report on Form 10-K), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during our fourth fiscal quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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
- 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, it used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2009, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, CCR LLP ("CCR"), independently assessed the effectiveness of our internal control over financial reporting as of December 31, 2009 and issued an attestation report, which appears in the "Report of Independent Registered Public Accounting Firm" which is included in "Part II, Item 8 –Financial Statements and Supplementary Data."

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Except for the information about our Code of Ethics below, the information required by this Item 10 is incorporated by reference from our definitive proxy statement for our 2010 Annual Meeting of Stockholders (the "Proxy Statement").

We maintain a Code of Business Conduct and Ethics ("Code") that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including our independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates our expectations of our employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of our Code is published on our web site at www.delcath.com under "Investor - Corporate Governance." We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions on our web site.

Item 11. Executive Compensation

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required for this Item is incorporated by reference from our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements: The following Financial Statements and Supplementary Data of Delcath and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:

Balance Sheets at December 31, 2009 and 2008

Statements of Operations for the years ended December 31, 2009, 2008, and 2007 and cumulative from inception (August 5, 1988) to December 31, 2009

Statements of Other Comprehensive Loss for the years ended December 31, 2009, 2008, 2007 and cumulative from inception (August 5, 1988) to December 31, 2009

Statements of Stockholders' Equity, cumulative from inception (August 5, 1988) to December 31, 2009

Statements of Cash Flows for the years ended December 31, 2009, 2008, and 2007 and cumulative from inception (August 5, 1988) to December 31, 2009

Notes to Financial Statements

1.
2.
2. Financial Statement Schedule: See "Schedule II—Valuation and Qualifying Accounts" in this section of this Annual Report on Form 10-K.
3.

3. Exhibits: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Delcath Systems, Inc.
Schedule II – Valuation and Qualifying Accounts
Years ended December 31, 2009, 2008 and 2007
(in millions)

		Additions		
	Balance at beginning	Charged to costs and expenses	Charged to revenue	Balance at end of period
2009				
Deferred tax asset valuation allowance	13.6	5.9	—	$19.5
2008				
Deferred tax asset valuation allowance	10.4	3.2	—	$13.6
2007				
Deferred tax asset valuation allowance	8.5	1.9	—	$10.4

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DELCATH SYSTEMS, INC.

/s/ Eamonn P. Hobbs
Eamonn P. Hobbs
President and
Chief Executive Officer
(Principal Executive Officer)
Dated: February 26, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Eamonn P. Hobbs Eamonn P. Hobbs	President and Chief Executive Officer, and Director (Principal Executive Officer)	February 26, 2010
/s/ David A. McDonald David McDonald	Chief Financial Officer (Principal Financial Officer)	February 26, 2010
/s/Harold S. Koplewicz Harold S. Koplewicz, M.D.	Chairman of the Board	February 26, 2010
/s/ Laura Philips Laura Philips, Ph.D.	Director	February 26, 2010
/s/ Richard Taney Richard Taney	Director	February 26, 2010
/s/ Robert Ladd Robert Ladd	Director	February 26, 2010
/s/ Pamela Contag Pamela Contag, Ph.D.	Director	February 26, 2010
/s/ Roger Stoll Roger Stoll, Ph.D.	Director	February 26, 2010

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Exhibit Index

Exhibit No.		Description
3.1		Amended and Restated Certificate of Incorporation of the Company, as amended to June 30, 2005 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed June 5, 2006 (Commission File No. 001-16133).
3.2		Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.1		Rights Agreement, dated October 30, 2001, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.7 to the Company's Form 8-A filed November 14, 2001 (Commission File No. 001-16133)).
4.2		Form of Underwriter's Unit Option Agreement between the Company and Roan/Meyers Associates, L.P. (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form SB-2 (Registration No. 333-101661)).
4.3		Form of Warrant to Purchase Shares of Common Stock issued pursuant to the Common Stock Purchase Agreement dated as of March 19, 2004 (incorporated by reference to Exhibit 4 to the Company's Current Report on Form 8-K filed March 22, 2004 (Commission File No,. 001-16133)).
4.4		Form of 2005 Series A Warrant to Purchase Shares of Common Stock issued pursuant to the Common Stock Purchase Agreement dated as of November 27, 2005 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed November 30, 2005 (Commission File No. 011-16133)).
4.5		Form of 2005 Series C Warrant to Purchase Shares of Common Stock issued pursuant to the Common Stock Purchase Agreement dated as of November 27, 2005 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed November 30, 2005 (Commission File No. 011-16133)).
4.6		Form of Warrant to Purchase Shares of Common Stock dated June 15, 2009 issued pursuant to the Subscription Terms dated as of June 9, 2009 between the Company and Capital Ventures International (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 10, 2009 (Commission File No,. 001-16133)).
10.1	*	2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.2	*	2001 Stock Option Plan (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2001 (Commission File No. 001-16133)).
10.3	*	2004 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's definitive Proxy Statement dated April 29, 2004 (Commission File No. 001-16133)).

10.4	*	2009 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's definitive Proxy Statement on Schedule 14A filed April 30, 2009 (Commission File No. 001-16133)).
10.5		Common Stock Purchase Agreement dated as of March 19, 2004 by and among the Company and the Purchasers Listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 22, 2004 (Commission File No. 001-16133)).

10.6		Registration Rights Agreement dated as of March 19, 2004 by and among the Company and the Purchasers Listed on Schedule I thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 22, 2004 (Commission File No. 001-16133)).
10.7		Common Stock Purchase Agreement dated as of November 27, 2005 by and among the Company and the Purchasers Listed on the Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2005 (Commission File No. 001-16133)).
10.8		Registration Rights Agreement dated as of November 27, 2005 by and among the Company and the Purchasers Listed on the Schedule I thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2005 (Commission File No. 001-16133)).
10.9		Voting Agreement dated as of November 27, 2005 by and between the Company, the purchasers listed on Exhibit A to the Common Stock Purchase Agreement dated as of November 27, 2005 and Vertical Ventures LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 30, 2005 (Commission File No. 001-16133)).
10.10	*	Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.11	*	Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.12	*	Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.13		Settlement Agreement, dated as of October 8, 2006, by and between the Company, Laddcap Value Partners LP, Laddcap Value Advisors LLC, Laddcap Value Associates LLC, any affiliate of the foregoing, and Robert B. Ladd (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 12, 2006 (Commission File No. 001-16133)).
10.14		Modification Agreement dated April 9, 2007 between the Company, Laddcap Value Partners, LP, Laddcap Associates, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 16, 2007 (Commission File No. 001-16133)).
10.15		Lease Agreement between Rockbay Capital Management, L.P. and the Company, dated as of July 9, 2007 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 30, 2007 (Commission File No. 001-16133)).

10.16	Consent of Master Landlord to the Sublease, dated August 21, 2007 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 30, 2007 (Commission File No. 001-16133)).
10.17	Placement Agency Agreement dated September 18, 2007 by and among the Company, Canaccord Adams Inc. and Think Equity Partners LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 24, 2007 (Commission File No. 001-16133)).
10.18	Form of Subscription Agreement in connection with the Company's September 2007 registered direct offering (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 24, 2007 (Commission File No. 001-16133)).

10.19		Form of Warrant issued to investors in connection with the Company's September 2007 registered direct offering (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 24, 2007 (Commission File No. 001-16133)).
10.20		Escrow Agreement dated September 18, 2007 between the Company, Canaccord Adams Inc., Think Equity Partners LLC and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 24, 2007 (Commission File No. 001-16133)).
10.21	†**	Cooperative Research and Development Agreement effective as of December 14, 2006 between the Company and the National Cancer Institute.
10.22		Form of Indemnification Agreement dated April 8, 2009 between the Company and members of the Company's Board of Directors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 10, 2009 (Commission File No. 001-16133)).
10.23		Subscription Agreement (Subscription Terms) dated as of June 9, 2009 between the Company and Capital Ventures International (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 10, 2009 (Commission File No. 001-16133)).
10.24		Placement Agency Agreement dated June 9, 2009 between Piper Jaffray & Co. and the Company (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed June 10, 2009 (Commission File No. 001-16133)).
10.25	*	Separation and General Release Agreement dated as of July 5, 2009 between the Company and Richard L. Taney (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 7, 2009 (Commission File No. 001-16133)).
10.26	*	Employment Agreement dated as of July 6, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 7, 2009 (Commission File No. 001-16133)).
10.27	*	Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.28	*	Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.29		Lease with Option to Purchase between Fitzgerald Brothers Beverages, Inc. and the Company, dated as of September 1, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 3, 2009 (Commission File No. 001-16133)).

10.30	*	Employment Agreement dated as of September 13, 2009 between the Company and David A. McDonald (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.31	*	Employee Stock Option Grant Letter dated as of September 14, 2009 between the Company and David A. McDonald (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).

10.32	*	Restricted Stock Agreement dated as of September 14, 2009 between the Company and David A. McDonald (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.33	*	Employment Agreement dated as of September 30, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D. (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed October 5, 2009 (Commission File No. 001-16133)).
10.34	* **	Employee Stock Option Grant Letter dated October 20, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D.
10.35	* **	Restricted Stock Agreement dated as of October 20, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D.
10.36		Underwriting Agreement between Cowen and Company, LLC and the Company, dated as of November 12, 2009 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed November 18, 2009 (Commission File No. 001-16133)).
23	**	Consent of CCR LLP
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a-14(a).
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a-14(a).
32.1	**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

* Indicates management contract or compensatory plan or arrangement.

** Filed herewith.