DELCATH SYSTEMS INC
Form 10-K
March 03, 2009

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, 2008

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 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 issuer, based on the closing sales price of $2.46 per share, was $54,859,341 as of June 30, 2008.

At February 19, 2009, the registrant had outstanding 25,383,354 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's Proxy Statement for its 2009 Annual Meeting of Stockholders is incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this 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 Form 10-K.

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Item 1. Business.

General

Delcath Systems, Inc. ("we," "us," "our," "Delcath," or the "Company") is a development stage company that has developed innovative device designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. The Company was incorporated in the State of Delaware in 1988 and since its inception has focused its efforts on the development of a single product, The Delcath PHP System™, that isolates the circulatory system of a specific organ or body region in order to deliver high dose chemotherapy or other therapeutic agents directly to that diseased organ or body region. The first application being tested with our system is for the treatment of cancers of the liver. The Delcath PHP System™ isolates the liver from the patient's general circulatory system and delivers high doses of the chemotherapeutic drug, melphalan hydrochloride, directly to tumors in the liver while avoiding most of the toxicities that normally result from such high doses of drug. In 2006, the Company began a Phase III clinical trial to support the United States Food and Drug Administration (the "FDA") approval process for the Delcath PHP System™, however, the Delcath PHP System™ is not currently approved by the FDA, and it cannot be marketed in the United States without FDA pre-market approval. The trial is ongoing, and the Company expects to complete enrollment of the trial in 2009.

Delcath has also received approval from the FDA to begin working on a Phase III clinical trial that will focus on the effectiveness of the Delcath PHP System™ in administering high-dose doxorubicin as compared with standard systemic treatment with the drug sorafenib for the treatment of primary liver cancer. The Company is also conducting Phase II clinical trials, testing the Delcath PHP System™ with the drug melphalan against hepatocellular tumors (primary liver cancer) and neuroendocrine and adenocarcinoma tumors that have spread to the liver, as well as melanomas metastatic to the liver that have received certain prior regional treatment.

In the future, we plan to conduct pre-clinical and clinical trials using the Delcath PHP System™ with other chemotherapy agents to treat cancer in the liver. Since our inception, we have raised approximately $52.7 million in aggregate funds (net of fundraising expenses), and we have invested approximately $29.4 million of those funds in research and development costs associated with development and testing of the Delcath PHP System™. In the years ended December 31 2008, 2007 and 2006 we invested $5.4 million, $4.2 million and $2.7 million, respectively on research and development activities. Delcath maintains a website at www.delcath.com.

Strategy

We are seeking to establish the Delcath PHP System™ as the standard technique for delivering high dose chemotherapy agents directly to the liver and to further develop and test the Delcath technology so that it can be used in the treatment of other liver diseases as well as in other organs or regions of the body. We seek to generate growth, revenues and high returns for our stockholders through a strategy that includes the following elements:

- Complete our clinical trial and obtain FDA pre-market approval for use of the Delcath PHP System™ with melphalan to treat malignant melanoma that has spread to the liver. Our highest priority is completing this Phase III clinical trial and related data preparation, statistical analysis and filing of necessary regulatory documents associated with an application for FDA pre-market approval of the commercial sale of the Delcath PHP System™ in the United States for the treatment of melanoma that has spread to the liver. Clinical trials of the Delcath PHP System™ are currently being enrolled at eleven hospitals in the U.S., led by the National Cancer Institute (the "NCI").

- Obtain approval to market the Delcath PHP System™ in the United States for the treatment of cancers in addition to melanoma in the liver. We are testing the 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 the drug melphalan.

- Test the Delcath PHP System™ with drugs other than melphalan for the treatment of cancers of the liver We have tested the drugs doxorubicin and 5-FU with our system in humans and we intend to evaluate other promising drug candidates for use with the System to treat other tumors in the liver.

- 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 limbs, kidneys, pancreas, and lungs.

- Investigate treatment of hepatitis using anti-viral drugs. We believe that our technology may be compatible with other compounds, including anti-virals, to treat other diseases of the liver such as hepatitis.

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- Improve our technology. We continue to identify improvements and modifications to our technology with the goal of increasing potential drug dosing, simplifying the procedure, shortening procedure recovery times and expanding the uses of the Delcath PHP System™. These changes may include new catheter designs, system architectures and the development of filters with affinity to specific agents.

- Introduce the Delcath PHP System™ into non-US markets. We may seek to establish strategic relationships with domestic or foreign firms that have an established presence or experience in certain foreign markets. Our strategy focuses on markets that have both a high incidence of liver disease and the public or private means to provide and pay for the medical treatments associated with our technology. We may explore arrangements with strategic partners who have experience in obtaining the necessary regulatory approvals and marketing of medical devices in markets that have high incidences of cancer and liver disease.

The Cancer Treatment Market

According to "Cancer Facts and Figures 2008," cancer remains the second leading cause of death in the United States exceeded only by heart disease. The most commonly used treatments for cancers of the liver include surgical resection, chemotherapy, radiation and hormone therapy.

The financial burden of cancer is great for patients, their families and society. "Cancer Facts & Figures 2008," estimates the overall costs of cancer to be $219.2 billion during 2007 including $89.0 billion for direct medical costs, $18.2 billion for indirect morbidity costs attributable to lost productivity due to illness and $112.0 billion for indirect mortality costs attributable to lost productivity due to premature death.

The Liver Cancer Market

Liver cancer is one of the most prevalent and lethal forms of cancer. There are two forms of liver cancer: primary and metastatic. Primary liver cancer is cancer that originates in the liver. Metastatic or secondary cancer is cancer that has spread from other places in the body to the liver. In our clinical trials, we are treating both primary liver cancer and metastatic cancers in the liver. According to the American Cancer Society's "Cancer Facts & Figures 2008," the five-year survival rate for liver cancer patients is approximately 10.8%, compared to 66% for all other forms of cancer combined. 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.

Metastatic 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. Once these cancer cells enter the liver and develop into tumors, they tend to grow very quickly. In many cases, patients die not as a result of their primary cancer, but from the tumors that develop in their liver. Humans cannot survive without a liver capable of performing its critical biological functions, which include converting food into energy and filtering toxins from the blood. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

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 in 2007. The incidence of liver cancer has been steadily increasing in the United States over the past two decades largely due to an increase in the rate of hepatitis

infection.

Primary liver cancer is particularly prevalent in Southern Europe, Asia and developing countries, where the primary risk factors for the disease are present. These risk factors include: hepatitis-B, hepatitis-C, relatively high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants. In Asia, liver cancer and diseases of the liver are one of the most prevalent lethal diseases in males under the age of 35. The largest need for effective treatments of primary liver cancer is found in Southern Europe and in Asia.

Current Liver Cancer Treatments

Limited effective treatment options are currently available for liver cancer, and they are generally associated with significant side effects and can even cause death. Traditional treatment options, discussed in more detail below, include surgery, liver transplant, chemotherapy, cryosurgery, percutaneous ethanol injection, radiation therapy, including selective internal radiation therapy, implanted infusion pumps and surgically isolated perfusion.

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Resection

Surgical resection is considered the “gold standard” treatment option for liver tumors, however, approximately 90% of liver tumors are unresectable, which means they do not qualify for surgical removal. For the patients who qualify for surgery, there can be significant complications related to the procedure. Recurrence of tumors is common, and in that event, surgery typically cannot be repeated.

By reducing the size and number of tumors by an amount sufficient to make resection feasible, we believe that, in some cases, delivery of drugs with the Delcath PHP System™ may allow for a surgical option for tumors that are currently inoperable. Chemotherapy can also be administered through the Delcath PHP System™ after resection with the objective of destroying micro metastases in the liver that may remain undetected, thus preventing or delaying any recurrence of tumor growth.

Transplant

Transplanting a healthy donor liver into a patient with a diseased liver is rarely performed due to the low availability of donor organs and the high probability of tumor recurrence within the transplanted liver.

Chemotherapy

The most prevalent form of liver cancer treatment is intravenous chemotherapy. The effectiveness of this treatment option can be dependent on the dose of chemotherapeutic drug administered. Generally, the higher the dosage of chemotherapy administered, the greater its ability to kill cancer cells, but due to the toxic side effects of chemotherapy agents, the higher the dosage administered, the greater the damage chemotherapy agents cause to healthy tissues. As a result, the high doses of chemotherapy that may be required to kill cancer cells can be highly toxic or even lethal to patients.

The side effects caused by melphalan, the drug in our current clinical trials, are similar to the side effects associated with a number of other chemotherapy agents. Melphalan can cause severe mucositis leading to ulceration of the mouth and digestive organs, can damage a patient’s immune system through destruction of bone marrow cells, and cause acute nausea, severe vomiting, dermatological problems and hair loss. The use of melphalan can be fatal even when administered with careful patient monitoring.

Recently, an oral chemotherapy, sorafenib, was approved as a treatment for patients with unresectable hepatocellular carcinoma (“HCC”) or primary liver cancer. Results of a clinical trial testing sorafenib demonstrated an increase in overall survival of patients receiving this drug when compared against patients receiving a placebo. The increased survival benefit was reported to be less than three months. Subsequent to the approval of sorafenib as a treatment for HCC, Delcath received approval from the FDA to initiate a Phase III trial for the treatment of primary liver cancer with the Delcath PHP System™ versus a control arm receiving sorafenib.

Cryosurgery

Cryosurgery is the destruction of cancer cells using sub-zero temperatures. During cryosurgery, multiple stainless steel probes are placed into the center of the tumor and liquid nitrogen is circulated through the end of the device into the tumor, effectively freezing it. Cryosurgery involves a cycle of treatments in which the tumor is frozen, allowed to thaw and then refrozen.

Percutaneous Ethanol Injection

Percutaneous ethanol injection, or PEI, involves the injection of alcohol into the center of the tumor. The alcohol causes cells to dry out and cellular proteins to disintegrate, ultimately leading to tumor cell death.

While PEI can be successful in treating some patients with primary liver cancer, it is generally considered less effective against large tumors. Complications can include pain and the potential introduction of alcohol into the bile ducts and major blood vessels. In addition, this procedure can cause cancer cells to be deposited along the needle track when the needle is being withdrawn from the tumor.

Radiation Therapy

Radiation therapy uses high dose x-rays or the delivery of localized radiation to kill cancer cells. Radiation therapy using x-rays is not considered an effective means of treating liver cancer and is rarely used for this purpose. A number of localized radiation delivery mechanisms are currently being used and tested, and may hold some effectiveness against certain types of liver cancers. 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.

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Radio Frequency Ablation

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. This procedure is used for patients with a limited number of smaller unresectable tumors.

Microwave Ablation

Microwave ablation is an experimental therapy similar to Radio Frequency Ablation that uses microwaves instead of electrical current to destroy tumor cells. Some physicians believe that the use of microwaves can enhance the targeting tumors when compared to Radio Frequency Ablation.

Chemoembolization

Chemoembolization is a commonly used therapy that involves the injection of a chemotherapeutic drug in combination with a chemical 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.

Hepatic Artery Infusion

Hepatic artery infusion involves the injection of chemotherapeutic drugs directly into the artery supplying blood to the liver. Because the chemotherapy agents pass from the liver into the patient's general circulation, hepatic arterial infusion has similar toxicities to systemic administration and limits the ability to administer higher doses of chemotherapy.

Implanted Infusion Pumps

Implanted infusion pumps can be used to target the delivery of chemotherapy agents to the tumor. The pump is surgically implanted under the skin and delivers regular doses of chemotherapeutic agents to a targeted area over time. This pump does not prevent the entry of chemotherapy agents into the patient's general circulation after it passes through the liver. As a result, this technique limits the ability to administer higher doses of chemotherapy.

Surgically Isolated Perfusion

Physicians have experimented with techniques to surgically isolate the liver from the general circulatory system and to achieve a targeted delivery of chemotherapy agents to the liver at higher than normal doses. In the 1980's, a physician in Germany published a surgical procedure that involved surgically clamping the arteries and veins supplying the liver with blood while infusing high dosages of chemotherapy agents directly into the liver. A blood filtration circuit reduced drug concentrations before returning the diverted blood to the patient. Regionalized isolated delivery can provide improved dosing while sparing patients from some of the drug's toxic effects on healthy tissue. The treatment was not broadly adopted by the medical community because it is highly invasive, and resulted in prolonged recovery times and long hospital stays at very high costs. The Delcath PHP System™ was designed to improve upon and overcome some of the shortcomings of this surgical approach.

Other Methods of Treatment

Other liver cancer treatments include gene therapy, hyperthermia and the use of biological response modulators, monoclonal antibodies and liposomes. Many of these treatment options are experimental, and their effectiveness is

either limited or unknown, or have dose limiting side effects.

Treatment with the Delcath PHP System™

The Delcath PHP System™ is designed to address the critical shortcomings of conventional intravenous chemotherapy for the treatment of various cancers. The Delcath PHP System™ isolates the liver from the patient's general circulatory system, allowing for the administration of high 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 removes substantially all of these high doses of chemotherapy from the blood before it is reintroduced to the patient's general circulatory system. By filtering out most of the high doses of drug, healthy tissues and organs are less likely to be exposed to the harmful side effects of these higher doses of chemotherapy. Based on human clinical data, we believe that the Delcath PHP System™ allows for higher chemotherapy doses to be delivered to the liver than can be administered by conventional intravenous delivery. By delivering higher doses of the chemotherapy agent to the liver than what would otherwise be possible via conventional chemotherapy, the treatment kills a higher number of cancer cells and may lead to better clinical outcomes.

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The Delcath PHP System™ kit includes the following disposable components manufactured for Delcath by original equipment manufacturers:

- 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.
- Extracorporeal filtration circuit — a blood tubing circuit containing disposable components used with a non-disposable blood pump which push the isolated blood through the System's filters and guide the cleansed blood back to the patient.
- Filters — two activated carbon hemoperfusion filters used to remove most of the chemotherapy agent from the isolated blood coming out of the liver before the blood is returned to the patient's general circulatory system.
- Return catheter — a thin-walled blood sheath used to deliver the filtered blood from the extracorporeal filtration circuit back into the patient's general circulatory system.
- Series of introducers and related accessories to properly place the catheters.

The double balloon catheter has one large passageway and three smaller passageways. Each of two low-pressure occlusion balloons is inflated via two of the three smaller passageways. Blood flows out of the liver through the catheter's large passageway towards the filtration system. Attached to the large passageway, a separate access port is designed for sampling fluid or flushing the system. The third smaller passageway allows some blood exiting the legs and kidneys to bypass the isolated segment of the body and return normally to the heart.

The Delcath PHP System™ involves a series of three catheter insertions, each of which is made through the skin. During clinical test procedures, patients are treated with intravenous sedation. 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.

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 activated charcoal filters to remove most of the chemotherapy agent. The filtered blood is returned 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™. In time, we expect the procedure to be performed on an outpatient basis, with the patient resuming normal activities the day after the procedure is performed. An advantage of the Delcath PHP System™ is that the procedure is repeatable and we expect a patient to undergo an average of four treatments at approximately one-month intervals. A new disposable Delcath PHP System™ kit is used for each treatment.

Our Clinical Trials

Following completion of the Phase I trials at the NCI, Delcath met with the FDA to request approval to move directly from the completed Phase I study of melphalan to a Phase III trial of patients with melanoma metastatic to the liver. The FDA granted Fast Track review status to the protocol and allowed Delcath to submit the study under the provision of a Special Protocol Assessment ("SPA"). The FDA granted an SPA for this trial in March 2006. The protocol covered by the SPA Agreement calls for the treatment of 92 patients, equally randomized to either the Delcath PHP System™ treatment or to receive "Best Available Care" in the control arm of the trial. The primary efficacy endpoint for the trial is hepatic progression free survival, which is defined as the length of time a patient is both alive and free from any significant increase in the size of the tumor within their liver (free from progression). Under the SPA Agreement, a patient treated as part of the Best Available Care control group who has experienced progression of their liver disease and thus met the primary trial endpoint may be eligible to cross over and be treated with the Delcath PHP System™. Patients are currently being treated at the NCI and at ten additional clinical trial centers that were added to the trial during 2008.

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We intend to demonstrate that administering melphalan with the Delcath PHP System™ results in better patient treatment outcomes than those obtained from other available treatments in patients with malignant melanoma that has spread to the liver. Phase III clinical trials are a prerequisite for FDA approval of Delcath's pre-market application. These trials are intended to demonstrate that the administration of melphalan through the Delcath PHP System™ is safe and effective for the treatment of melanoma in the liver.

The FDA pre-market approval we are currently pursuing is for the administration of melphalan with the Delcath PHP System™ to treat patients suffering from metastatic melanoma that has spread to the liver. If we are granted this approval, we plan to seek additional FDA pre-market approvals for using the Delcath PHP System™ with other chemotherapy agents and for the treatment of other liver cancers. The process of applying for and obtaining regulatory approvals involves rigorous pre-clinical and clinical testing. The time, resources and funds required for completing necessary testing and obtaining approvals is significant, and FDA pre-market approval may never be obtained. If we fail to raise additional capital or to enter into strategic partnerships to finance this testing or if we fail to obtain the required approvals, our potential growth and the expansion of our business would likely be limited.

Prior to starting the Phase III trials, we conducted Phase I and II clinical trials at several centers in the United States and overseas under investigational device (IDE) and investigational new drug (IND) exemptions granted by the FDA. The trials were designed to demonstrate the System's safety and "functionality," or its ability to administer to and extract from the liver approved and marketed chemotherapy agents. Patients in these earlier trials had primary liver cancer or other cancers that had spread to the liver. Patients were treated with melphalan, doxorubicin or 5-FU. These trials demonstrated that the Delcath PHP System™ was capable of extracting up to 85% of the chemotherapy agent administered to the liver and permitted the delivery of higher dosages of these three different anticancer agents to the liver, while at the same time minimizing the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.

We believe the results of the clinical trials we have conducted indicate that the Delcath PHP System™ delivered:

- more chemotherapy agent to the tumor site;
- less chemotherapy agent to the general circulation than what would be delivered by administration of the same dose of drug by intravenous means; and
- high dosing without the systemic toxicities that the patient would have experienced if similar dosing was administered using conventional intravenous delivery.

The FDA has classified the Delcath PHP System™ as a drug delivery system, which requires us to obtain approval of new labeling for the higher doses of drug being used in the clinical trials. The clinical trials are designed to provide the data to support this labeling change.

During 2008, we added ten clinical trial sites to the Phase III clinical trial in order to speed patient accrual and expand the geographic and institutional experience with the Delcath PHP System™.

Our Clinical Trial and Agreement with the National Cancer Institute (NCI)

In 2001, we announced that the NCI approved a Phase I clinical study protocol for administering escalating doses of the chemotherapy agent melphalan through the Delcath PHP System™, to patients with metastatic and unresectable cancer of the liver.

The Phase I clinical trial conducted at the NCI has been completed and has been followed by a Phase II study treating patients with primary liver cancers, adenocarcinomas and neuroendocrine cancers that have metastasized to the liver. NCI is also the coordinating center for the Phase III study treating patients with melanoma metastatic to the liver. In 2007, we expanded the Phase II multi-histology clinical trial to include a fourth arm consisting of patients with metastatic melanoma in the liver who have previously received certain regional therapies. The Phase II and Phase III clinical trials are subject to the terms and conditions of the Cooperative Research and Development Agreement (the "CRADA") between us and the NCI.

On March 29, 2007, following the December 14, 2006 expiration of the initial five-year term of the CRADA between Delcath and the NCI, we announced that the agreement had been extended for an additional five years. This extension enhances and expands the initial CRADA by providing for collaboration between us and the NCI in the joint development and evaluation of the Delcath PHP System™ device to deliver high-dose melphalan to patients, and to evaluate the use of additional chemotherapy agents with the Delcath PHP System™. Under the agreement, the Surgery Branch of the NCI will work towards completion of the Delcath Phase III trial for patients with metastatic melanoma in the liver using the drug melphalan, and serve as the coordinating center for this multi-center trial, of up to the current maximum of 15 clinical trial centers authorized by the FDA.

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Research for Hepatitis Treatment

Another disease that attacks the liver is viral hepatitis. Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses including hepatitis A, B, C, D and E, but usually refers to hepatitis B and C. Hepatitis B and C are serious and common infectious diseases of the liver, affecting millions of people throughout the world. The World Health Organization estimates that more than 2 billion people alive today have been infected with hepatitis B at some time in their lives. Of these, about 350 million remain infected chronically. Up to 3% of the world's population may harbor hepatitis C infection, with 4 million carriers in Europe alone. The Center for Disease Control (the "CDC") estimated there were 65,000 new cases of hepatitis B and hepatitis C in the U.S. in 2006. According to the CDC, up to 1.4 million Americans have chronic hepatitis B virus infections and 3.2 million have chronic hepatitis C virus infections. The incidence of viral hepatitis in the United States and worldwide is increasing. The CDC further predicts the number of deaths from hepatitis C will triple in the next two decades. The estimated cost, including treatment and lost productivity due to sickness, is estimated to be over $700 million per year for hepatitis B and over $600 million per year for hepatitis C. The long-range effects of some forms of hepatitis can include massive death of liver cells, chronic active hepatitis, cirrhosis and hepatoma. The current treatment for viral hepatitis is limited and includes long-term injections of interferon alpha, which is similar to chemotherapy in its toxicity and dosage limitations.

We plan on evaluating studies to determine the feasibility of using the Delcath PHP System™ to administer higher doses of anti-viral drugs in the treatment of viral hepatitis. Prior to human clinical trials, we may perform testing on different filters to determine their ability to remove certain antiviral agents and conduct animal testing to determine the effect of high dose antiviral therapy when delivered into the liver.

Other Organs and Body Regions

Future applications of the Delcath technology may include the treatment of pancreatic tumors, biliary tumors, renal tumors and tumors of the limbs. Delcath has begun to explore modifications to our core technology to allow for treatment of these areas of the body using our perfusion technology. We are initiating discussions with physicians who have shown interest in furthering the development of some of these systems and plan to conduct bench and animal testing to establish the feasibility of specific drugs for the treatment of these tumors.

Sales and Marketing

If we receive FDA approval, we may enter into collaboration with an existing medical device marketer or we may market the system ourselves. If we develop our own sales force, we intend to focus 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 trials. We plan to focus our efforts on two distinct groups of medical specialists in these comprehensive cancer centers:

- oncologists who have primary responsibility for the cancer patient; and
- interventional radiologists who are physicians specialized in working with catheter-based systems.

We plan to hire a sales and marketing director as we approach the expected filing of our application for approval of the Delcath PHP System™ to the FDA We will then consider establishing a group of sales representatives to market the System in the United States.

In addition, 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.

Since we plan to sell the Delcath PHP System™ to a large number of hospitals and physician practices, we do not expect to be dependent upon one or a few customers.

Market acceptance of the Delcath PHP System™ will depend upon:

- the ability of our clinical trials to demonstrate improved patient outcomes versus alternative treatment alternatives;
- our ability to educate physicians on the use of the system and its benefits compared to other treatment alternatives; and
- our ability to obtain acceptable levels of reimbursement for the Delcath PHP System™ from third party healthcare payers by demonstrating that the System results in improved patient outcomes at a reasonable cost.

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Third-Party Reimbursement

Because the Delcath PHP System™ is characterized by the FDA as an experimental device, 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 devices and 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 continue to 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 manufacturing and performance specifications that are on file with the FDA.

The catheters and catheter accessories contained within the Delcath PHP System™ kit are being manufactured domestically by the OEM division of B. Braun Medical, Inc. of Germany. B. Braun has demonstrated that the components it manufactures meet Delcath's specifications. B. Braun's manufacturing facility is ISO 9000 approved, which will ultimately qualify the System to the standards set for European markets. We have not entered into a written agreement with B. Braun to manufacture the System either for the clinical trials or for commercial sale.

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. The components manufactured by Medtronic have been cleared by the FDA for other applications but are considered experimental under Delcath's Investigational Device Exemption (IDE) and must comply with manufacturing and performance specifications for the Delcath PHP System™ that are on file with the FDA. Medtronic's manufacturing facility is also ISO 9000 approved and, thus, the components it manufactures may be used in European markets.

The Company currently obtains the activated charcoal filters used with the System from Clark Research and Development. These activated charcoal filters were previously marketed in the U. S. and overseas for blood detoxification, but their use within the Delcath PHP System™ is considered experimental under Delcath's IDE approved by the FDA. Delcath is working with this and other filter manufacturers to develop improved filters for use within the Delcath PHP System™.

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.

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The Delcath PHP System™ competes with all forms of liver cancer treatments including, surgical resection, liver transplant, chemotherapy, cryosurgery, percutaneous ethanol injection, radiation therapy, selective internal radiation therapy, radio frequency ablation, chemoembolization, hepatic artery infusion, implanted infusion pumps, surgically isolated perfusion, gene therapy, hyperthermia and the use of biological response modulators, monoclonal antibodies and liposomes. Many of Delcath's 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 or patent protection, in which case the likelihood of our achieving meaningful revenues or profitability will be substantially reduced.

Government Regulation

General. 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, it requires FDA approval of a pre-market application prior to the commercial distribution of the Delcath PHP System™.

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. 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 currently approved, we will be seeking a revised label of melphalan for use with the Delcath PHP System™. 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.

Medical Devices. The Delcath PHP System™ is a Class III medical device. Class III medical devices are subject to the most stringent regulatory controls to assure reasonable safety and effectiveness. FDA pre-market approval is required for all Class III medical devices. An application for pre-market approval must be supported by data about the device and its components, including the manufacturing and labeling of the device, the results of animal and laboratory testing and data from human clinical trials. The conduct of Phase III clinical trials is subject to extensive regulation and to ongoing oversight by FDA as well as the institutional review boards ("IRB") at hospitals and research centers that conduct the trials. Before commencing clinical trials, we obtained an investigational device exemption ("IDE") providing for the initiation of clinical trials. We also obtained approval of our investigational plan, including the proposed protocols and informed consent statement that patients sign before undergoing treatment with the Delcath PHP System™, by the FDA and the institutional review boards at the sites where the trials are being conducted.

Since our protocol has received fast-track designation, we believe that the FDA will review our pre-market application 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 approval of the Delcath PHP System™.

If the FDA's evaluations of the application, clinical study sites and manufacturing facilities are favorable, the FDA will issue either an approval letter or an "approvable letter". An approvable letter contains a list of conditions that must be met to obtain full approval of an application. If and when those conditions are met to the satisfaction of the FDA, the agency will issue an order of approval for the application, authorizing commercial marketing of the device for the specific indications approved. If the FDA's evaluation of the application, the clinical study sites or the manufacturing

facilities is not favorable, the FDA may deny approval of the application or issue a “not approvable letter.” The FDA may also determine that additional pre-clinical testing or human clinical trials should be performed before approval, or that post-approval studies must be conducted.

Approved medical devices 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 medical device reporting regulations require that we provide information to the FDA on any deaths or serious injuries that may have been caused or contributed to by the use of marketed device 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™. Delcath plans to file a 505(b)(2) New Drug Application with the FDA to request this change to the label. We have no assurance that the FDA will approve our application for a change to the current label.

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The Phase III clinical trial protocol using melphalan which has been approved by the FDA is designed to obtain approval of both new drug labeling and a pre-market approval application providing for the use of melphalan with the Delcath PHP System™. The trial protocol was approved by both the FDA division that approves new drugs and the division that reviews applications to market new devices. All of the data generated in the trial will be submitted to both of these FDA divisions.

Under the Food, Drug and Cosmetic Act, the Delcath PHP System™ cannot be marketed until the new drug application, or supplemental new drug application, and the pre-market approval application, are approved, and then only in conformity with any conditions of use set forth in the approved labeling.

Orphan Drug Regulation. On November 18, 2008, we announced that the FDA had granted Delcath two orphan-drug designations for the drug melphalan. Delcath was granted designations of the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma.

A human drug application or supplement for a prescription drug product that has been designated as a drug for a rare disease or condition (orphan drug) is not subject to standard FDA application fees. Sponsors of orphan drugs can also request a waiver from annual product and establishment fees.

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.

Foreign Regulation. In order for our products to be marketed in Asia, Europe, Latin America 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 pre-market approval or clearance.

In order for us to market and sell the Delcath PHP System™ in foreign jurisdictions, we must obtain required regulatory approvals or clearances and otherwise comply with extensive regulations. 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 European Economic Area (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. Delcath has begun the process of seeking the CE Mark for the Delcath PHP System™.

Delcath has also begun the process of applying for an import license for the Delcath PHP System™ into China. Under Chinese regulations, prior to considering the importation of the Delcath PHP System™ into China Delcath must first have obtained FDA pre-market approval for the Delcath PHP System™ in the United States. Marketing our device in other parts of the world including China requires the obtaining of country specific regulatory approvals and compliance with extensive local regulations.

Patents, Trade Secrets and Proprietary Rights

Our success depends in large 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 the following seven United States patents, as well as twenty corresponding foreign patents in 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

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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 are always seeking patent improvements that we identify through manufacturing and clinical use of the Delcath PHP System™ which allow us to expand the use of the System beyond the treatment of cancers in the liver.

U.S. Patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. Delcath intends to seek extension for some of our patents after pre-market approval.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. 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.

Employees

As of December 31, 2008 we had six full-time employees. In January, 2009, we hired a Controller and intend to recruit additional personnel in connection with the research, development, manufacturing and marketing of our products. None of our employees is represented by a union and we believe relationships with our employees are good.

In addition to our full-time employees, we engage the services of medical, scientific, and financial consultants.

Internet Access to Periodic Reports

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "Commission"). Our Commission filings (File No. 1-16133) are available to the public free of charge over the Internet at the Commission's web site at http://www.sec.gov, and on our web site at http://www.delcath.com.

You may also read and copy any document we file at the Commission's public reference room located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may request copies of these documents by writing to the Commission and paying a fee for the copying cost.

Item 1A. Risk Factors

You should carefully consider the specific risks set forth below relating to our business and our Company before making an investment decision. The risks and uncertainties we have described are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently consider immaterial also may adversely affect our Company. The following risk factors should be read carefully in connection with evaluating our business and the forward-looking statements that we make in this report and elsewhere (including oral statements) from time to time. If any of the following risks and uncertainties actually occurs, our business, financial condition or operating results may be materially and adversely affected. In this event, the trading price of our securities may decline and you may lose part or all of your investment.

Risks Related to Our Business and Financial Condition

If we are not successful in the development and commercialization of the Delcath PHP System™, or if we are unable to market and sell the product, we will not generate operating revenue or become profitable.

The Delcath PHP System™, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs for the treatment of a variety of diseases, is our only product, and our entire focus has been the development and commercialization 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, 2008, we have incurred cumulative net losses of approximately $45.8 million. For the years ended December 31, 2008 and 2007, we incurred net losses of approximately $6.9 million and $3.7 million, respectively.

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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 and 2007. Please see the detailed discussion of our sales of securities described in Note 3 to our 2008 financial statements included in this report. We received proceeds of approximately $5.6 million from private placements we completed in 2004; approximately $2.2 million on exercise of warrants and options in 2004; approximately $2.5 million from a private placement we completed in 2005; approximately $5.5 million on exercise of warrants and options in 2005; approximately $5.1 million on exercise of warrants and options in 2006; approximately $1.3 million on exercise of options in 2007; and approximately $13.3 million from a registered direct offering we completed in 2007. As of December 31, 2008, we had cash and cash equivalents of approximately $10.8 million.

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 pre-market approval.

Before we can obtain approval to sell our product commercially, we will need pre-market approval from the FDA. While we believe that we have sufficient capital to conduct our operations for this year, our current resources may not be sufficient to complete the Phase III clinical trial using melphalan or other clinical trials that we may pursue and will be insufficient to fund the costs of commercializing the Delcath PHP System™, which will be significant. Many of the costs of conducting clinical trials are uncertain and not within our control, including (i) the possibility that the FDA may require additional trials (ii) the charges payable to each current or prospective clinical test site which is based on the number of participants in the trial; (iii) the amount of the fee per patient, which is individually negotiated with each test site; (iv) the number of patients that may be required to be enrolled in any particular trial; (v) the location of the test site which can affect other costs, including the costs of retaining a clinical research organization, monitoring and other out of pocket costs such as travel; (vi) the actual number of treatments performed per patient in each clinical trial; and (vii) the possible increase or reduction in trial costs billed to us where a patient's insurer refuses or agrees to cover certain treatment expenses. We do not know if additional financings will be available when needed, or if they are available, that they will be available on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to complete our trials, obtain regulatory approvals or sell the Delcath PHP System™ commercially.

If we are unable to obtain additional funding, our general business operations will be harmed.

While we believe that we have sufficient capital to conduct current operations, we will require additional capital for research and development and for clinical trials. Our liquidity and capital requirements will depend on numerous factors, including: our research and product development programs, including clinical studies; the timing and costs of our various United Sates and foreign regulatory filings, obtaining approvals and complying with regulations; the timing of product commercialization activities; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the impact of competing technological and market developments. We do not know if additional financing will be available when needed, or if it is available, if it will be available on acceptable terms. Insufficient funds may require us to curtail or stop our research and development activities.

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

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

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

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

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Risks Related to FDA and Foreign Regulatory Approval

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

If the FDA grants pre-market 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 System would be limited to its use with that drug in treating that disease. Thereafter, physicians could use the System for the treatment of other cancers or use other drugs ("off-label" use), but we could not market it for such uses, unless we obtained separate FDA approval to market the System for use with those other drugs or diseases.

If we do not obtain FDA pre-market approval, we may not be able to export the Delcath PHP System™ to foreign markets, which will limit our sales opportunities.

If the FDA does not approve our application for pre-market approval for the Delcath PHP System™, we will not be able to export the Delcath PHP System™ from the United States for marketing abroad unless approval has been obtained from one of a number of developed nations. We may not be able to obtain approval from one or more countries where we would like to sell the Delcath PHP System™. 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.

Conduct of clinical trials and obtaining FDA pre-market approval 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 completion of these clinical trials will be dependent on a number of factors, some of which are out of our control.

Completion of our clinical trials depends heavily on the ability of the clinical test sites to identify patients to enroll in the clinical trials. The population of appropriate patients (i.e., patients with melanoma that has metastasized to the liver) is limited. Any significant delay in completing clinical trials or in the FDA's response to our submission, or a requirement by the FDA for us to conduct additional trials, 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 the Company to halt the trials. We may not be able to resume our trials or be able to launch trials overseas if the FDA were to halt the United States trials.

In October 2007, Delcath received a letter from the FDA recommending that we temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath PHP System™ in anticipation of a meeting with the Agency to discuss certain gastrointestinal ("GI") safety concerns. The recommendation was issued by the FDA following reports by Delcath of four serious adverse GI events, which may have been related to the infusion of melphalan. Following receipt of this letter, we decided to voluntarily defer enrollment of new patients in our Phase III and Phase II trials pending that meeting.

During a meeting at the FDA that was attended by senior reviewers from both the Drug and Device arms of the FDA, the Principal Investigator at the NCI presented an analysis of the previously reported gastrointestinal toxicities and of the changes incorporated into the trial protocols to prevent a recurrence of those toxicities. These changes had been previously approved by the NCI Institutional Review Board and were subsequently approved by the Data Safety

Monitoring Board that monitors the Phase III trial. Following that meeting, we were notified in writing by the FDA that the studies could proceed and we resumed patient enrollment in the trials less than a month after receiving the October letter.

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

- the FDA may put the Phase III and/or Phase II trials on clinical hold;
- additional serious adverse events in the clinical trials could occur;
- other regulators or institutional review boards may not authorize, or may delay, suspend or terminate the clinical trial program due to safety concerns.

If similar events were to occur in the future, our clinical trials, and as a result, our business, operations and stock price could be materially impacted.

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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 pre-market approval is granted.

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

The Delcath PHP System™ is currently characterized by the FDA as an experimental device. 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 one of our suppliers fails to meet such requirements or if we change suppliers, the successful completion of the clinical trials and/or the commercialization of the Delcath PHP System™ could be jeopardized.

The components of the Delcath PHP System™ must be manufactured in accordance with manufacturing and performance specifications of the Delcath PHP System™ on file with the FDA and meet good manufacturing practice requirements. Many of the components of the Delcath PHP System™ are manufactured by sole-source suppliers. If any of our suppliers fails to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for the System, which could jeopardize our ability to supply the Delcath PHP System™ to the market.

We do not have any contracts with suppliers for the manufacture of components for the Delcath PHP System™. If we are unable to obtain an adequate supply of the necessary components, we may not be able to complete our clinical trials.

We do not have long term supply contracts with suppliers of components for the Delcath PHP System™. Certain components are available from only a limited number of sources. Components of the Delcath PHP System™ are currently manufactured for us in small quantities for use in our pre-clinical 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, commercialization of the Delcath PHP System™ could be delayed.

We have limited experience in marketing products and lack adequate personnel to market and sell products, and as a result, we may not be successful in marketing and selling the Delcath PHP System™ even if we receive FDA pre-market approval.

Delcath has not previously sold, marketed or distributed any products and currently does not have the personnel, resources, experience or other capabilities to market the Delcath PHP System™. Our success will depend upon our ability to attract and retain skilled sales

and marketing personnel or our reaching an agreement with a third party to market our product. 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.

Market acceptance of the Delcath PHP System™ will depend on substantial efforts and expenditures in an area with which we have limited experience.

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;

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- Whether the Delcath PHP System™ replaces 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 result in a short product life cycle for the Delcath PHP System™.

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, our profitability will be substantially reduced and the Delcath PHP System™ could have a short product life cycle.

The loss of key personnel could adversely affect our business.

Our Chief Executive Officer is responsible for the operation of our business, and we have entered into an employment agreement with him for his services. The loss of his services could delay our completion of the clinical trials, our obtaining FDA pre-market 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.

Risks Related to Patents, Trade Secrets and Proprietary Rights

Our success depends in large part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Companies in the medical device industry may use intellectual property infringement litigation to gain a competitive advantage. If this type of litigation is successful, a third party may be able to obtain an injunction prohibiting us from offering our product. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to defend our intellectual property rights may also affect our financial condition adversely.

Risks Related to Products Liability

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

Clinical trials, manufacturing and product sales may expose us to liability claims from the use of the Delcath PHP System™. Though participants in clinical trials are generally required to execute consents and waivers of liability, a court might find such consents and waivers of liability to be ineffective or invalid. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in the clinical trials and result in the loss of physician endorsement. A successful products liability claim or recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry some clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

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Risks Related to an Investment in Our Securities

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

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

- 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;
- conditions generally affecting the healthcare and cancer treatment industries; and
- the success of our operating strategy.

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

Future sales of our common stock may cause our stock price to decline.

The market price of our common stock has historically been volatile. During the three years ended December 31, 2008, the range of the high and low sales prices of our common stock have ranged from a high of $6.00 (during the quarter ended June 30, 2006) to a low of $0.82 (during the quarter ended December 31, 2008).

Sales of substantial amounts of common stock, or the perception that such sales could occur, could have an adverse effect on prevailing market prices for our common stock.

Our insiders beneficially own a significant portion of our stock.

As of December 31, 2008, our executive officers, directors and affiliated persons beneficially owned approximately 12.2% 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.

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 and warrants.

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.

BACK

Our Common Stock is listed on the NASDAQ Capital Market. If we fail to meet the requirements of the NASDAQ Capital Market for continued listing, our Common Stock could be delisted.

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

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

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

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

A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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

We currently occupy 3,400 square feet of office space at 600 Fifth Avenue, New York, N.Y. under a sublease which expires in July 2010. We have occupied these facilities since September 2007, and the space is adequate for our

current needs. If we require different or additional space in the future, we believe that satisfactory space will be available in or near our current facility, although it is possible that additional facilities and equipment will not be available on reasonable or acceptable terms, if at all. We believe that our properties are adequately covered by insurance.

We believe that our facilities and equipment are in good condition and are suitable for our operations as presently conducted and for our foreseeable future operations.

We do not invest in real estate, interests in real estate, real estate mortgages or securities of or interests in persons primarily engaged in real estate activities.

Item 3. Legal Proceedings

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

BACK

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

Our common shares trade on the NASDAQ Capital Market under the symbol "DCTH."

The following table sets forth the per share range of high and low sales prices of our Common Stock for the periods indicated as reported on the Nasdaq Capital Market:

Common Stock Price Range

	2008	
	High	Low
Quarter ended March 31, 2008	$ 2.22	$ 1.20
Quarter ended June 30, 2008	2.67	1.66
Quarter ended September 30, 2008	2.55	1.26
Quarter ended December 31, 2008	1.54	0.82

	2007	
	High	Low
Quarter ended March 31, 2007	$ 4.93	$ 3.14
Quarter ended June 30, 2007	4.95	3.63
Quarter ended September 30, 2007	4.63	3.29
Quarter ended December 31, 2007	3.62	0.92

As of February 19, 2009 there were approximately 85 stockholders of record of our Common Stock.

Dividend Policy

We have never paid cash dividends on our Common Stock and anticipate that we will continue to retain our earnings, if any, to finance the growth of our business.

Performance Graph

The graph below compares the cumulative total returns, including reinvestment of dividends, if applicable, on the Company's Common Stock with the returns on companies in the NASDAQ Market Index and an Industry Group Index (Hemscott Industry Group 513 - Drug Delivery).

The chart displayed below is presented in accordance with the requirements of the Securities and Exchange Commission. The graph assumes a $100 investment made on December 31, 2003 and the reinvestment of all dividends, if applicable. Stockholders are cautioned against drawing any conclusions from the data contained in this section, as past results are not necessarily indicative of future performance.

BACK

	12/2003	12/2004	12/2005	12/2006	12/2007	12/2008
Delcath Systems, Inc.	100.00	330.77	373.63	406.59	203.30	130.77
NASDAQ Composite	100.00	110.06	112.92	126.61	138.33	80.65
Peer Group	100.00	168.22	152.79	142.11	152.23	77.42

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2008 with respect to our compensation plans under which our equity securities are authorized for issuance:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding option, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Plan Category	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	1,460,000	$ 3.44	380,000
Equity compensation plans not approved by security holders	-	-	-
Total	1,460,000	$ 3.44	380,000

(1) Includes shares issued and issuable under the Delcath Systems, Inc. 2004 Stock Incentive Plan.

BACK

Additional Information

We did not sell any equity securities during our 2008 fiscal year that were not registered under the Securities Act of 1933, as amended, and have not previously been described in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

During the fourth quarter of our 2008 fiscal year, there were no purchases of our common stock made by or on behalf of Delcath or any of our "affiliated purchasers" (as defined in Rule 10b-18(a)(3) of the Securities Exchange Act of 1934, as amended).

Item 6. Selected Financial Data

The selected consolidated financial data presented below under the caption "Statement of Operations Data" and "Balance Sheet Data" as of the end of and for each of the years in the five-year period ended December 31, 2008, are derived from the financial statements of Delcath Systems, Inc. The financial statements as of December 31, 2008 and 2007 and for each of the three-year period ended December 31, 2008 (and cumulative from inception) and the report thereon, are included under Item 8, "Financial Statements and Supplementary Data." The selected financial data should be read in conjunction with the financial statements and the related notes thereto and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended December 31,				
(Dollars in thousands)	2008	2007	2006	2005	2004
Statement of Operations Data					
Costs and expenses	$ 8,066	$ 6,913	$ 11,699	$ 3,112	$ 3,367
Operating loss	8,066	6,913	11,699	3,112	3,367
Net loss	6,865	3,664	10,952	2,865	3,266
Loss per share	(0.27)	(0.16)	(0.55)	(0.18)	(0.28)

	Year Ended December 31,				
(Dollars in thousands)	2008	2007	2006	2005	2004
Balance Sheet Data					
Current assets	$ 11,341	$ 18,091	$ 8,760	$ 12,920	$ 7,338
Total assets	11,359	18,106	8,764	12,928	7,352
Current liabilities	1,152	1,677	670	330	565
Stockholder's equity	10,207	16,429	8,093	12,598	6,787

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

Forward-Looking Statements

This Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth in this annual report on Form 10-K for the year ended December 31, 2008. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding

our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words “may,” “continue,” “estimate,” “intend,” “plan,” “will,” “believe,” “project,” “expect,” “ar similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

These forward-looking statements speak only as of the date of this Form 10-K. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

BACK

We are a medical technology company that develops and manufactures an innovative device designed to administer high dose chemotherapy and other therapeutic agents directly to diseased organs or regions of the body. We are currently focusing on the development of a single product, the Delcath PHP System™, for the treatment of tumors of the liver. Based on human clinical data, we believe that the Delcath PHP System™ allows physicians to deliver significantly higher chemotherapy doses to the liver than could be administered by conventional intravenous delivery.

The Delcath PHP System™ is a disposable kit consisting of various catheters, filters, and a tubing circuit used during cancer treatment to isolate the liver from the patient's general circulatory system. Our system allows for ultra-high doses of chemotherapy agents to be directed at a patient's liver while at the same time limiting the exposure of healthy tissue and organs to the harmful effects of those chemotherapeutic agents. By providing higher dosing of chemotherapy agents than would otherwise be possible through conventional chemotherapy, we believe that treatment with the Delcath PHP System™ is more effective than conventional treatment at killing cancer cells and preventing new cancer cell formation.

In 2006 we began a Phase III clinical trial to support a pre-market approval application for use of the Delcath PHP System™ with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is being conducted under the Food and Drug Administration's ("FDA") Special Protocol Assessment ("SPA"). Patients enrolled in this study currently receive treatment at the National Cancer Institute, or NCI, which serves as the coordinating center for this multi-center trial or at one of the other participating centers. The trial is currently approved for expansion to a maximum of 15 centers. In April 2008, the Institutional Review Board of the University of Maryland Medical Center agreed to participate in our Phase III study. In June 2008, St. Luke's Cancer Center, the Albany Medical Center, the Atlantic Melanoma Center of Atlantic Health and the University of Texas Medical Branch joined this clinical trial. In the third quarter, Swedish Medical Center of Colorado, John Wayne Cancer Institute, Providence Health Systems, and Moffitt Cancer Center agreed to join the clinical trial. In the fourth quarter of 2008, University of Pittsburgh Medical Center agreed to join the trial which brings the total to eleven centers. Each of the center's Institutional Review Board ("IRB") has approved our treatment protocol. Critical to expediting completion of this trial, the Western International Review Board, or WIRB, has also approved our 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, 2008 we have enrolled a total of 47 patients of the expected 92-patient trial. We expect to complete patient enrollment in this study in 2009. Once the FDA grants approval, we plan to conduct additional pre-clinical and clinical trials on the use of the Delcath PHP System™ with other chemotherapy agents used to treat cancer in the liver and seek additional FDA pre-market approvals.

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 adenocarcenoma cancers that have spread to the liver. In 2007 an additional arm was added to the Phase II trial to treat patients with metastatic melanomas that have spread to the liver who have received prior surgical isolated hepatic perfusion. Based on promising initial clinical results, we plan to focus our efforts on enrolling patients for the treatment of metastatic neuroendocrine cancer. We have currently enrolled 23 of the 25 patients required for the neuroendocrine arm of the trial and we anticipate that we will complete patient enrollment in this arm of the study in 2009.

As indicated above, the Company is focusing on enrolling patients in the neuroendocrine arm of the Phase II study. The other two arms treating colorectal cancer and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the FDA concerning a clinical trial that will focus on the effectiveness of the Delcath PHP System™ in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September 2008, the Company received a conditional approval from the FDA to begin working on that trial.

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 pre-market approval.

During the next twelve months we plan to hire additional personnel to support the development of the Delcath PHP System™. In June 2008 and July 2008 we hired two senior executives. We hired a Chief Medical Officer to oversee the expansion of clinical activity, moving us towards the conclusion of our first Phase III clinical trial. We also hired a Senior Vice President for Regulatory Affairs and Quality Systems, a position newly created to manage the extensive FDA process. 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 a strategic alliance with appropriate partners to fund future activities. We cannot be assured that the pace of patient enrollment will meet our projections, 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 any of our products.

BACK

The Company's expenditures are highly variable and are dependent upon the number and pace of patients enrolled in our clinical trials. We expect that the amount of capital required for our trials will increase over the coming twelve months due to the increased number of patients enrolled at newly added clinical trial centers. We believe that we have sufficient capital for operations through 2009 and to substantially advance our ongoing Phase III trial.

We are a development stage company, and since our inception we have raised approximately $52.7 million (net of fundraising 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 expect to continue to incur significant and increasing net losses 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 years. 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 adding new sites to our ongoing clinical trials and increasing our efforts to enroll additional patients in these trials. As we seek FDA approval and get our product to market we expect that our capital expenditures will increase significantly.

At December 31, 2008, cash and cash equivalents totaled $10,787,137, as compared to $7,886,937 at December 31, 2007. Nearly all of our available funds are currently invested in money market funds and certificates of deposit, which are reflected in our financial statements as cash and cash equivalents. At December 31, 2007, in addition to cash and cash equivalents totaling $7,886,937 we had $9,878,700 invested in treasury bills which were listed separately from cash and cash equivalents in our financial statements. At December 31, 2007, treasury bills plus cash and cash equivalents had a combined value of $17,765,637.

During the twelve months ended December 31, 2008, we used $6,723,277 of cash in our operating activities. This amount compares to $5,569,197 used in our operating activities during the comparable twelve month period ended December 31, 2007. The increase of $1,154,080, or 20.7%, is primarily due to accelerated clinical development costs relating to all facets of the Delcath PHP System™. We expect that our cash allocated to operating activities will increase significantly as we aggressively move toward the full enrollment and completion of our first Phase III clinical trial, and continue to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our current clinical trials through 2009.

At December 31, 2008, the Company’s accumulated deficit was approximately $47.3 million. Because our business does not generate any positive cash flow from operating activities, we will likely need to raise additional capital 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.

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 offering in 2007. Please see the detailed discussion of our various sales of securities described in Note 3.

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, 2008 (in millions):

	Payments Due by Period					
	Total	2009	2010	2011	2012	2013
Operating Activities:						
Research Activities	$ 3.0	$ 1.0	$ 1.0	$ 1.0	$ -	$ -
Operating Leases	0.3	0.2	0.1	-	-	-

BACK

We have an operating lease for office space that will expire on July 30, 2010, with a rent obligation of $221,000 per annum.

Our five year CRADA for the development of the Delcath PHP System™ with the NCI expired on December 14, 2006 and has been 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 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.

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 for the next twelve months, but anticipate that we will require additional working capital to continue our operations after the year ended December 31, 2009. 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, 2008; Comparisons of Results of the Years Ended December 31, 2007 and 2006

We have operated at a loss for our entire history. 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.

We had a net loss for the twelve months ended December 31, 2007, of $3,663,506, which is $7,288,099, or 66.6%, less than the net loss from continuing operations for the same period in 2006. This substantial decrease is primarily due to the resolution of various legal matters that had been instituted in 2006, and their related extraordinary costs which were incurred in 2006. There were, however, additional expenses relating to a five-year extension to the CRADA with the NCI that initially expired in December 2006. This extension was necessary for continuing and expanding the collaboration between the Company and the NCI, but will result in greater costs to the Company. The agreement with the NCI required that the annual payments to them be increased five-fold from the previous agreement. Additionally, the warrants that were issued in 2007 as part of the Company's sale of common stock and warrants are considered to be derivatives and are subject to valuation and adjustment on a quarterly basis. This resulted in the recording of derivative instrument income for the year of $2,717,000 which substantially reduced the net loss from continuing operations.

General and Administrative Expenses

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.

General and administrative expenses decreased by 70.3% from $8,980,424 during the twelve months ended December 31, 2006, to $2,671,782 for the twelve months ended December 31, 2007. While legal fees incurred during 2007 were substantially less than those incurred in 2006 and would have resulted in a greater reduction in period-to-period expenses due to the resolution of various legal matters, additional charges to general and administrative expenses were incurred in 2007 by share-based compensation for options granted to new members of the Board of Directors, options granted to the President and Chief Executive Officer, and options granted to newly hired management employees. Further, the cashless exercise of options by outgoing members of the Board of Directors resulted in additional charges to general and administrative expenses during 2007.

Research and Development Expenses

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 have seen a marked increase in the rate of patient enrollment and treatment which has had a noticeable impact on our research and development expenses.

BACK

During the twelve months ended December 31, 2007, we incurred $4,241,517 in research and development costs, which is a 56% increase as compared to $2,718,084 of research and development costs during 2006. This change was primarily due to additional expenses with the NCI, as well as accelerated clinical development costs relating to all facets of the Delcath PHP System™ which required greater expense but will hasten the progress toward final approval. In addition, the Company allocated share-based compensation for stock and options awarded to personnel involved with research and development related initiatives.

Interest Income

Interest income generated during 2008 and 2007 is from our money market accounts and treasury bills. 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.

During the twelve months ended December 31, 2007, we had interest income of $532,793, as compared to interest income of $620,403 for the same period in 2006, a 14% change. This decrease is primarily due to a reduced cash position in 2007 from that in 2006. The net proceeds from the sale of the Company's common stock and warrants in September 2007 were received on the last day of the third quarter of fiscal 2007 and therefore did not have a material impact on annual interest income.

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 SFAS No. 109, "Accounting for Income Taxes," 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 as defined under FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109."

The Company has adopted the provisions of SFAS 123R. SFAS 123R establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, 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). Effective January 1, 2006, the Company adopted the modified prospective approach and, accordingly, prior period amounts have not been restated. Under this approach, the Company is required to record compensation cost for all share-based payments granted after the date of adoption based upon the grant date fair value, estimated in accordance with the provisions of SFAS 123R, and for the unvested

portion of all share-based payments previously granted that remain outstanding based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123. The Company has expensed its share-based compensation for share-based payments granted after January 1, 2006 under the ratable method, which treats each vesting tranche as if it were an individual grant.

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS No. 157 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 SFAS No. 157 did not have a material effect on the carrying values of the Company's assets.

SFAS No. 157 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, SFAS No. 157 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).

BACK

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 received 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. During the third quarter ending September 30, 2008, the restriction on the common stock held lapsed and as a result the fair value of the stock is calculated using the closing stock price (unadjusted) at December 31, 2008. The investment is classified as an available for sale security and had a fair value on December 31, 2008 of $22,000, which included a gross unrealized loss of $24,200, 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 in the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract. In 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 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 warrants. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280). The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances; including the Company's inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature in certain circumstances. Accordingly, the warrants have been accounted for as derivative instrument liabilities, which are subject to mark-to-market adjustment in each period. As a result, for the twelve month period ended December 31, 2008, the Company recorded pre-tax derivative instrument income of $1,103,682. The resulting derivative instrument liability totaled $448,318 at December 31, 2008. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 1.20%, volatility of 68.97% and an expected life equal to the September 24, 2012 contractual life of the warrants.

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Item 8. Financial Statements and Supplementary Data

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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, 2008 and 2007, 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, 2008 and cumulative from inception (August 5, 1988) to December 31, 2008. We also have audited the Company's internal control over financial reporting as of December 31, 2008, 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, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2008 and cumulative from inception (August 5, 1988) to December 31, 2008 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, 2008, 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 27, 2009

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Balance Sheets as of December 31, 2008 and 2007

	December 31, 2008	December 31, 2007
Assets		
Current assets		
Cash and cash equivalents	$ 10,787,137	$ 7,886,937
Investments - treasury bills	200,710	9,878,700
Investment – marketable equity security	22,000	—
Prepaid expenses	331,346	325,452
Total current assets	$ 11,341,193	$ 18,091,089
Property and equipment, net	17,489	15,037
Total assets	$ 11,358,682	$ 18,106,126
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 703,489	$ 125,278
Derivative instrument liability	448,318	1,552,000
Total current liabilities	1,151,807	1,677,278
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	253,553	252,593
Additional paid-in capital	57,292,685	56,626,533
Deficit accumulated during development stage	(47,315,163)	(40,450,278)
Accumulated other comprehensive loss	(24,200)	—
Total stockholders' equity	10,206,875	16,428,848
Total liabilities and stockholders' equity	$ 11,358,682	$ 18,106,126

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Operations
for the Years Ended December 31, 2008, 2007, and 2006 and
Cumulative from Inception (August 5, 1988) to December 31, 2008

	Year ended December 31,			Cumulative from inception (August 5, 1988) To December 31, 2008
	2008	2007	2006	
Costs and expenses				
General and administrative expenses	$ 2,687,688	$ 2,671,782	$ 8,980,424	$ 22,779,099
Research and development costs	5,378,335	4,241,517	2,718,084	29,397,416
Total costs and expenses	8,066,023	6,913,299	11,698,508	52,176,515
Operating loss	(8,066,023)	(6,913,299)	(11,698,508)	(52,176,515)
Derivative instrument income	1,103,682	2,717,000	—	3,820,682
Interest income	299,956	532,793	620,403	2,786,748
Other (expense)/income	(202,500)	—	126,500	(76,000)
Interest expense	—	—	—	(171,473)
Net loss	$ (6,864,885)	$ (3,663,506)	$ (10,951,605)	$ (45,816,558)
Common share data				
Basic and diluted loss per share	$ (0.27)	$ (0.16)	$ (0.55)	
Weighted average number of basic and diluted common shares outstanding	25,300,703	22,321,488	19,906,932	

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Other Comprehensive Loss
for the Years Ended December 31, 2008, 2007, and 2006 and Cumulative from Inception (August 5, 1988) to December 31, 2008

	Years Ended December 31,			
	2008	2007	2006	Cumulative
Other comprehensive loss:				
Net loss	$ (6,864,885)	$ (3,663,506)	$ (10,951,605)	$ (45,816,558)
Change in unrealized loss on investments	(24,200)	—	—	(24,200)
Other comprehensive loss	$ (6,889,085)	$ (3,663,506)	$ (10,951,605)	$ (45,840,758)

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2008, 2007, and 2006 and Cumulative from Inception (August 5, 1988) to December 31, 2008

	Common stock $.01 par value											
	Issued		In Treasury		Outstanding		Preferred Stock $0.01 Par Value		Class A Common Stock $0.01 Par Value		Class B Common Stock $0.01 Par Value	Additional Paid-in Capital
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount
nection with the formation of the ust 22, 1988	621,089	$6,211	-	$ -	621,089	$6,211	-	$ -	-	$ -	-	$ (5,211)
ck, August 22, 1988	-	-	-	-	-	-	-	-	2,000,000	20,000	-	480,000
to relevant technology g fully achieved, March 8, 1990	-	-	(414,059)	(4,141)	(414,059)	(4,141)	-	-	-	-	-	4,141
er 2, 1990	-	-	17,252	173	17,252	173	-	-	-	-	-	24,827
non stock at $7.39 per share and ock at $2.55 per share), January	-	-	46,522	465	46,522	465	-	-	-	-	416,675	4,167 1,401,690
st 30, 1991	-	-	1,353	14	1,353	14	-	-	-	-	-	- 9,987
mber 31, 1992	-	-	103,515	1,035	103,515	1,035	-	-	-	-	-	- 1,013,969
ding 10,318 warrants, each to of common stock at $10.87), July	-	-	103,239	1,032	103,239	1,032	-	-	-	-	-	- 1,120,968
mber 19, 1996	-	-	39,512	395	39,512	395	-	-	-	-	-	- 999,605
ding 78,438 warrants each to of common stock at $10.87) in version of short-term cember 22, 1996	58,491	585	98,388	984	156,879	1,569	-	-	-	-	-	- 1,703,395
mber 31, 1997	53,483	535	-	-	53,483	535	-	-	-	-	-	- 774,465
tions	13,802	138	3,450	35	17,252	173	-	-	-	-	-	- 30,827
mpensation for consulting 10.87 per share based on a 1996	2,345	23	828	8	3,173	31	-	-	-	-	-	- 34,454
nection with exercise of	21,568	216	-	-	21,568	216	-	-	-	-	-	- 234,182
ry 16, 1998	34,505	345	-	-	34,505	345	-	-	-	-	-	- 499,655
mber 24, 1998	3,450	35	-	-	3,450	35	-	-	-	-	-	- 56,965
settlement of a dispute with a 1.45 per share, the price l 17, 1998	(3,450)	(35)	-	-	(3,450)	(35)	-	-	-	-	-	- (4,965)

tions	8,626	86	-	-	8,626	86	-	-	-	-	-	67,414
ling 5,218 warrants each to of common stock at $14.87),	46,987	470	-	-	46,987	470	-	-	-	-	-	775,722
nection with exercise of	2,300	23	-	-	2,300	23	-	-	-	-	-	24,975
14, 2000	230,873	2,309	-	-	230,873	2,309	-	-	-	-	-	499,516
referred stock	690,910	6,909	-	-	690,910	6,909	-	-	-	-	-	992,161
rred stock	833,873	8,339	-	-	833,873	8,339	-	(2,000,000)	(20,000)	(416,675)	(4,167)	15,828
ling 1,200,000 warrants each to of common stock at $6.60),	1,200,000	12,000	-	-	1,200,000	12,000	-	-	-	-	-	5,359,468

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2008, 2007, and 2006 and Cumulative from Inception (August 5, 1988) to December 31, 2008

	Common stock $.01 par value								
	Issued		In Treasury		Outstanding			Deficit Accumulated	
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	Additional Paid-in Capital	During Development Stage	Total
res issued as compensation stock sale	85,000	850	-	-	85,000	850	(850)	-	
20 stock options (including 20 warrants each to chase one share of mmon stock at $6.00), ued as compensation	-	-	-	-	-	-	3,800	-	3,8
m of fractional common res cancelled after year 00 stock splits	(36)	(1)	-	-	(36)	(1)	1	-	
ck warrants (150,000 at 00 and 150,000 at $6.60) ued as compensation	-	-	-	-	-	-	198,000	-	198,0
e of stock on April 3, 2002	243,181	2,432	-	-	243,181	2,432	265,068	-	267,5
purchases of stock, vember and December 02			(28,100)	(281)	(28,100)	(281)	(50,822)	-	(51,1
ortization since inception compensatory stock options	-	-	-	-	-	-	3,760,951	-	3,760,9
feiture since inception of ck options	-	-	-	-	-	-	(1,240,780)	-	(1,240,1
e of stock (including 95,155 warrants to chase one share of mmon stock at $0.775) on y 20, 2003 including derwriter's exercise of over otment option	3,895,155	38,952	-	-	3,895,155	38,952	1,453,696	-	1,492,0
ceeds from sale of unit ion, 2003	-	-	-	-	-	-	68	-	
ercise of warrants, 2003	1,730,580	17,305	-	-	1,730,580	17,305	1,273,895	-	1,291,2
e of stock, 2004	2,793,975	27,940	-	-	2,793,975	27,940	5,622,690	-	5,650,6
ercise of Warrants, 2004	20,265	203	-	-	20,265	203	26,547	-	26,7
ck options issued as mpensation, 2004	-	-	-	-	-	-	5,222	-	5,2
ercise of warrants, 2005	4,841,843	48,419	-	-	4,841,843	48,419	7,637,183	-	7,878,4

ercise of stock options, 05	659,000	6,590	-	-	659,000	6,590	569,180	-	575,1
ck options issued as mpensation, 2005	-	-	-	-	-	-	8,270	-	8,2
e of stock, November, 05	753,013	7,530	-	-	753,013	7,530	2,302,471	-	2,310,0
ares issued as mpensation, 2005	36,925	369	-	-	36,925	369	103,056	-	103,4
ficit accumulated from eption to December 31, 05	-	-	-	-	-	-	-	(24,336,562)	(24,336,5
ance at December 31, 2005	18,877,753	$ 188,778	(28,100)	$ (281)	18,849,653	$ 188,497	$ 38,244,566	$ (25,835,167)	$ 12,597,8
sting of stock options, 2006	-	-	-	-	-	-	446,000	-	446,0
ck options issued as mpensation, 2006	-	-	-	-	-	-	505,282	-	505,2
ercise of warrants, 2006	1,606,928	$ 16,069	-	-	1,606,928	$ 16,069	4,877,586	-	4,893,6
ercise of stock options, 06	104,182	1,042	-	-	104,182	1,042	295,024	-	296,0
ares issued in connection h settlement of Consent icitation lawsuit, 2006	100,000	1,000	-	-	100,000	1,000	305,000	-	306,0
loss, 2006	-	-	-	-	-	-		(10,951,605)	(10,951,6
ance at December 31, 2006	20,688,863	$ 206,889	(28,100)	$ (281)	20,660,763	$ 206,608	$ 44,673,458	$ (36,786,772)	$ 8,093,2

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2008, 2007, and 2006 and Cumulative from Inception (August 5, 1988) to December 31, 2008

	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	Accumulated Other Comprehensive Loss
,	715,413	7,154	-	-	715.413	7,154	1,793,029	-	-
l n,	50,000	500	-	-	50,000	500	210,500	-	-
n k 07	3,833,108	38,331	-	-	3,833,108	38,331	8,995,936	-	-
n ,	-	-	-	-	-	-	953,610	-	-
7	-	-	-	-	-	-	-	(3,663,506)	-
,	25,287,384	$ 252,874	(28,100)	$ (281)	25,259,284	$ 252,593	$ 56,626,533	$ (40,450,278)	$ -$
,	970	10	-	-	970	10	1,940	-	-
l n,	95,000	950	-	-	95,000	950	205,950	-	-
n	-	-	-	-	-	80,666	80,666	-	-
n	-	-	-	-	-	-	377,596	-	-

,									
ss									
	-	-	-	-	-	-	-	-	(24,200)
8	-	-	-	-	-	-	-	(6,864,885)	-
,		$					$		
	25,383,354	253,834	(28,100)	$ (281)	25,355,254	$ 253,553	57,292,685	$ (47,315,163)	$ (24,200)

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, 2008, 2007, and 2006 and
Cumulative from Inception (August 5, 1988) to December 31, 2008

	Year ended December 31,			Cumulative from inception (August 5, 1988) to December 31, 2008
	2008	2007	2006	
Cash flows from operating activities:				
Net loss	$ (6,864,885)	$ (3,663,506)	$ (10,951,605)	$ (45,816,558)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock option compensation expense	379,546	1,404,610	1,042,448	5,360,266
Stock and warrant compensation expense	287,566	211,000	306,000	1,144,278
Depreciation expense	5,861	4,323	3,835	51,762
Amortization of organization costs	—	—	—	42,165
Derivative liability fair value adjustment	(1,103,682)	(2,717,000)	—	(3,820,682)
Changes in assets and liabilities:				
Increase in prepaid expenses	(5,894)	(263,535)	(35,000)	(331,346)
Decrease in interest receivable	—	—	91,574	—
Increase (decrease) in accounts payable and accrued expenses	578,211	(545,089)	340,297	500,988
Net cash used in operating activities	(6,723,277)	(5,569,197)	(9,202,451)	(42,869,126)
Cash flows from investing activities:				
Purchase of equipment, furniture and fixtures	(8,313)	(15,641)	—	(69,252)
Purchase of short-term investments	(200,710)	(9,878,700)	(5,424,548)	(37,571,452)
Purchase of marketable equity securities	(46,200)	—	—	(46,200)
Proceeds from maturities of short-term investments	9,878,700	2,408,302	14,114,036	37,370,742
Organization costs	—	—	—	(42,165)
Net cash provided by (used in) investing activities	9,623,477	(7,486,039)	8,689,488	(358,327)
Cash flows from financing activities:				
	—	14,652,450	5,098,555	52,657,764

Net proceeds from sale of stock and exercise of stock options and warrants				
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	—	14,652,450	5,098,555	53,812,090
Increase in cash and cash equivalents	2,900,200	1,597,214	4,585,592	10,787,137
Cash and cash equivalents at beginning of period	7,886,937	6,289,723	1,704,131	—
Cash and cash equivalents at end of period	$ 10,787,137	$ 7,886,937	$ 6,289,723	$ 10,787,137
Supplemental cash flow information:				
Cash paid for interest	$ —	$ —	$ —	$ 171,473
Supplemental non-cash activities:				
Cashless exercise of stock options	$ 1,950	$ 451,000	$ 91,166	$ 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	$ —	$ 4,269,000	$ —	$ 4,269,000

See Accompanying Notes to these Financial Statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Financials Statements
for the Years Ending December 31, 2008, 2007 and 2006

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

(a) Description of Business

Delcath Systems, Inc. (the "Company") is a development stage company that develops and manufactures an innovative device designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. The Company was incorporated in the State of Delaware in 1988 and since its inception has focused its efforts on the development of a single product, the Delcath PHP System™, for the treatment of tumors of the liver.

In 2006, the Company began a Phase III clinical trial to support a pre-market approval application for use of the Delcath PHP System™ with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is ongoing, and the Company hopes to complete enrollment of the trial in 2009. In 2004, the Company began a multi-arm Phase II clinical trial for use of the Delcath PHP System™ with certain other cancers that have spread to the liver and metastatic melanomas that have spread to the liver and have received certain prior regional treatment. The Company is focusing on enrolling patients in the neuroendocrine arm of that study. The other two arms treating metastatic colorectal cancer and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the FDA concerning a clinical trial that will focus on the effectiveness of the Delcath PHP System™ in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September the Company received a conditional approval from the FDA to begin working on that trial. To date, the Delcath PHP System™ has not been approved by the FDA.

(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 and Equipment

Property and equipment (primarily furniture and fixtures) are recorded at cost and are being depreciated on a straight line basis over the estimated useful lives of the assets of five years. Accumulated depreciation totaled $51,665 at December 31, 2008 and $45,804 at December 31, 2007. Depreciation expense for the years ended December 31, 2008, 2007 and 2006 was $5,861, $4,323, and $3,835, 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

In June 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 ("FIN No. 48"). The interpretation contains a two step approach to recognizing and measuring uncertain tax positions accounted for in accordance with FASB Statement 109. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is

more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. The Company adopted FIN No. 48 as of January 1, 2007. The adoption of FIN No. 48 did not have any material impact on the Company's financial statements

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The Company accounts for income taxes following the asset and liability method in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting for 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 are prepared on the cash basis of accounting. 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 Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" ("SFAS 123R"). SFAS 123R establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, 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 SFAS 123R. 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 SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities," as amended, 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, 2008 and 2007, the Company did not have any derivative instruments that were designated as hedges.

Derivative instrument income of $1,103,682 and $2,717,000 for the years ended December 31, 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 placement. See Note 7 for additional information.

(g) Fair Value Measurements

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, Fair Value Measurements ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 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.

SFAS 157 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, SFAS 157 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).

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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.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115 ("SFAS 159"). This statement permits all entities to choose, at specified election dates, to measure eligible items at fair value (the "fair value option"). A business entity must report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected must be recognized in earnings as incurred and not deferred. This statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company has concluded there is no impact resulting from the adoption of SFAS 159.

In October 2008, the FASB issued Staff Position No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active" (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157, which the Company adopted as of January 1, 2008, in cases where a market is not active. The Company has considered the guidance provided by FSP 157-3 in its determination of estimated fair values as of December 31, 2008.

(h) Net Loss per Common Share

For the years ended December 31, 2008, 2007 and 2006 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

The Company considers highly liquid debt instruments with original maturities of three months or less at date of acquisition to be cash equivalents.

(k) Investments

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 received 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. At September 30, 2008 the sale restriction on the stock being held had 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 September 30, 2008 of $38,000 which included a gross unrealized loss of $8,200, which is included as a component of comprehensive loss.

The Company accounts for its investments in debt and equity instruments under Statement of Financial Accounting Standards, or SFAS, No. 115, “Accounting for Certain Investments in Debt and Equity Securities” and FASB Staff Position, or FSP, No. 115-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,” or FSP 115-1. 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 2008, marketable securities are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of shareholders’ equity. We follow the guidance provided by FSP 115-1, 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.

BACK

(l) Reclassifications

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

(m) Accounting Pronouncements Not Yet Adopted

Disclosures about Derivative Instruments and Hedging Activities

In March 2008, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 161, "Disclosures about Derivative Instruments and Hedging Activities" (“SFAS 161”), which changes the disclosure requirements for derivative instruments and hedging activities. SFAS 161 requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This Statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company has not yet determined the effect, if any, that SFAS 161 will have on its financial statements.

Accounting for Collaborative Arrangements

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 will be effective for the Company on January 1, 2009. The Company has not yet determined the effect, if any, that EITF 07-1 will have on its financial statements.

Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities” (“FSP EITF 03-6-1”). FSP EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in FASB Statement of Financial Accounting Standards No. 128, “Earnings per Share.” FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. The Company has not yet determined the effect, if any, that FSP EITF 03-6-1 will have on its financial statements.

Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)” (FSP APB 14-1). FSP APB 14-1

specifies that issuers of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. The amount allocated to the equity component represents a discount to the debt, which is amortized into interest expense using the effective interest method over the life of the debt. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is not permitted. The Company has not yet determined the effect, if any, that FSP APB 14-1 will have on its financial statements.

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Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an entity's Own Stock

In June 2008, the FASB ratified EITF Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock" (EITF 07-5). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies on the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. The Company has not yet determined the effect, if any, that EITF 07-5 will have on its financial statements.

(2) Investments

In accordance with SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, investments are reported at fair value on the Company’s balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income/ (loss) as a separate component of stockholders’ (deficiency) equity. If a decline in the fair value of a marketable security below the Company’s cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. To date, only temporary impairment charges have been recorded.

The Company’s investments are recorded at fair value and consist of one United States Treasury Bill with an original maturity of six months, various certificates of deposit and common stock in Aethlon Medical, Inc.

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 received 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, 2008 of $22,000 which included a gross unrealized loss of $24,200, which is included as a component of comprehensive loss.

The Company’s investments have not been significantly, adversely impacted by the recent disruption in the credit markets. However, if there is continued and expanded disruption in the credit markets, there can be no assurance that the Company’s investments will not continue to be adversely affected in the future.

(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%.

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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 in 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 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 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 warrants (see below). The warrants are 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. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280).

The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances, including its inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature. Accordingly, the warrants have been accounted for as derivative instrument liabilities which are subject to mark-to-market adjustment in each period. As a result, for the year ended December 31, 2008, the Company recorded pre-tax derivative instrument income of $1,103,682. The resulting derivative instrument liability totaled $448,318 at December 31, 2008. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 1.20%, volatility of 68.97% and an expected life equal to the September 24, 2012 contractual life of the warrants.

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 will vest in equal increments over three years on the anniversary date of the agreement. Total compensation expense of $484,000 will be expensed over the three year vesting period. The Company recorded $80,666 of compensation expense relating to the restricted stock agreement during 2008. The remaining compensation expense of $403,334 as of December 31, 2008 is expected to be recognized over the remaining 2.5 year vesting period.

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.

BACK

(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 and the 2004 Stock Incentive Plan (collectively, the "Plans") under which 300,000, 750,000 and 3,000,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, and stock grants. 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 terms and conditions of each award, the option price and the duration of each award.

During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and the 2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for 2008, 2007, and 2006 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2005	1,385,800	$ 0.71–3.59	$ 2.51	4.17
Granted	340,000	3.28	3.28	
Expired	(40,150)	2.78–3.59	3.33	
Exercised	(220,000)	1.03–3.59	2.96	
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

At December 31, 2008, 2007 and 2006, options for 1,286,666, 1,023,333, and 1,465,650, respectively, were exercisable at a weighted average exercise price of $3.42, $4.52, and $2.87 per share, respectively. The aggregate intrinsic value of options outstanding and exercisable at December 31, 2008 is $0.00. 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 $1.19 as of December 31, 2008, which would have been received by the option holders had those option holders exercised their options as of that date.

BACK

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, 2008, 2007 and 2006:

	Years Ended December 31,		
	2008	2007	2006
Risk-free interest rate	1.97%	4.60%	4.69%
Expected volatility of common stock	70.72%	57.56%	59.78%
Dividend yield	0.00%	0.00%	0.0%
Expected option term (in years)	2.60	2.58	2.50

No dividend yield was assumed because the Company has never paid a cash dividend. 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 the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, "Share-Based Payment." 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.

340,000 options were issued to the Board of Directors in November 2006. These options have an exercise price of $3.28, an expiration date of November 14, 2011 and vested immediately upon grant of the options.

200,000 options were issued to incoming members of the Board of Directors in May 2007. These options have an exercise price of $5.85 (150% of the common stock price at the date of grant), an expiration date of May 24, 2012 and vested immediately upon grant. An additional 150,000 options were issued under the same terms with the exception of an exercise price of $3.90.

100,000 options were issued to a new member of the Board of Directors in June 2007. These options have an exercise price of $7.14 (150% of the common stock price at the date of grant), an expiration date of June 4, 2012 and vested immediately upon issuance. An additional 50,000 options were issued under the same terms with the exception of an exercise price of $4.76.

125,000 options were issued to a two new employees in June 2007. The exercise prices for the options are $6.18 (25,000 options), $4.52 (50,000 options) and $4.12 (50,000 options). These options have an expiration date of June 1, 2012 and a vesting period of 36 months from the date of issuance. The Company has recognized compensation expense of $71,333 in 2008 relating to these option grants.

150,000 options were issued to the President and Chief Executive Officer in July 2007. The exercise prices for the options are $5.85, which represents 150% of the common stock price at the date of grant (100,000 options) and $3.90 (50,000 options). These options have an expiration date of July 2, 2012 and vested immediately upon issuance.

70,000 options were issued to four employees in November 2007. These options have an exercise price of $1.88, an expiration date of November 30, 2012 and vested immediately upon issuance.

50,000 options were issued to the President and Chief Executive Officer in January 2008. These options have an exercise price of $1.74, an expiration date of January 2, 2013 and vested immediately upon issuance. The Company recognized compensation expense totaling $33,873 upon grant of these fully vested options.

20,000 options were issued to an employee in May 2008. These options have an exercise price of $1.87, an expiration date of May 1, 2013 and a vesting period of 36 months from the date of issuance. The Company has recognized compensation expense of $4,180 in 2008 relating to these option grants.

70,000 options were issued to a new employee in June 2008. The exercise prices for the options are $3.45, which represents 150% of the common stock price at the date of grant (20,000 options) and $2.30 (50,000 options). These options have an expiration date of June 23, 2012 and a vesting period of 12 months from the date of issuance. The Company has recognized compensation expense of $35,055 in 2008 relating to these option grants.

BACK

50,000 options were issued to the President and Chief Executive Officer in July 2008. These options have an exercise price of $2.44, an expiration date of July 2, 2013 and vested immediately upon issuance. The Company has recognized compensation expense totaling $54,031 upon the grant of these full vested options.

150,000 options were issued to a new member of the Board of Directors in October 2008. The exercise prices for the options are $1.845 (100,000 options) and $1.23 (50,000) options. These options have an expiration date of October 14, 2013 and vested immediately upon issuance. The Company has recognized compensation expense totaling $67,713 upon the grant of these fully vested options.

150,000 options were issued to two new members of the Board of Directors in December 2008. The exercise prices for the options are $1.40 (75,000 options) and $1.25 (75,000 options). These options have expiration dates of December 5, 2013 and December 11, 2013 and vested immediately upon issuance. The Company has recognized compensation expense totaling $88,975 upon the grant of these fully vested options.

35,000 options were issued to two employees in December 2008. These options have an exercise price of $1.43, an expiration date of December 15, 2013 and vested immediately upon issuance. The Company has recognized compensation expense totaling $22,434 upon the grant of these fully vested options.

A summary of the Company's non-vested shares as of December 31, 2008 and changes during the twelve months ended December 31, 2008 is presented below:

	Non-Vested Options	
	Number of Shares	Weighted Average Fair Value
Non-vested at January 1, 2008	116,667	$ 1.70
Granted	90,000	0.99
Vested	(33,333)	1.66
Forfeited	–	–
Non-vested at December 31, 2008	173,334	$ 1.34

Total compensation expense recognized relating to stock option grants totaled $377,596, $953,610 and $505,282 in 2008, 2007 and 2006, respectively.

Additional compensation expense of $150,742, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 1.5 years.

BACK

(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, 2005	2,170,961	$ 1.02–3.91	$ 3.14	3.27
Issued	–			
Exercised	(1,606,928)	1.02–3.91	3.05	
Expired	–			
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	–	4.53	4.53	
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

(4) Income Taxes

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

	Year Ended		
	2008	2007	2006
Income taxes using U.S. federal statutory rate	$ (2,334,061)	$ (1,245,592)	$ (3,723,546)
State income taxes, net of federal benefit	(410,495)	(46,582)	(789,599)
Valuation allowance	3,226,441	1,813,480	4,483,576
Derivative charge	(375,252)	(923,780)	-
Expiration of net operating losses	–	207,061	96,959
Research and development credits	(211,208)	–	–
Other	104,575	195,413	(67,390)
	$ –	$ –	$ –

BACK

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

	2008	2007
Deferred tax assets:		
Employee compensation accruals	$ 861,000	$ 694,000
Accrual to cash	145,000	–
Research tax credits	211,000	–
Net operating losses	12,369,000	9,743,000
Total deferred tax assets	13,586,000	10,437,000
Deferred tax liability:		
Accrual to cash	–	78,000
Valuation allowance	13,586,000	10,359,000
Net deferred tax assets	$ –	$ –

As of December 31, 2008 and December 31, 2007, the Company had net operating loss carryforwards for federal income tax purposes of approximately $42,887,000 and $35,969,000, respectively. A portion of the federal amount, $12,557,000, 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 income tax regulations (Section 382). As a result of the limitation, $32,739,000 is available to offset future federal taxable income which expires through 2028. As of December 31, 2008 and December 31, 2007, the Company had net operating loss carryforwards for state income tax purposes of approximately $35,457,000 and $28,742,000, respectively, which expire through 2028.

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 $3.2 million, $1.8 million and $4.5 million in 2008, 2007, and 2006, respectively.

The Company has a tax benefit of approximately $338,000 related to the exercise of non qualified stock options. Pursuant to SFAS No. 123(R), 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 Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 ("FIN No. 48"). FIN 48 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 FIN 48, 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 FIN No. 48.

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, 2002 to December 31, 2008 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 Lease

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 $221,000, $98,584 and $87,376 for the years ended December 31, 2008, 2007 and 2006, respectively.

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(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 has been 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 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, $1,000,000, and $195,000 in expenses related to this agreement for the years ended December 31, 2008, 2007 and 2006, respectively.

(6) Contingencies

The Company is involved in certain legal proceedings and is subject to certain lawsuits, claims and regulations in the ordinary course of its business. Although the ultimate effect of these matters is often difficult to predict, management believes that their resolution will not have a material adverse effect on the Company's financial statements.

(7) Assets and Liabilities Measured at Fair Value

(a) Derivative Financial Instruments

Currently, the Company has allocated proceeds of warrants issued in connection with a private placement that were classified as a liability and accounted for as a derivative instrument in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock". 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 inputs associated with fair value determination are readily observable and as a result the instrument is classified within Level 2 of the fair-value hierarchy.

(b) Marketable Equity Securities

The Company owns 100,000 shares of common stock of AEMD. At December 31, 2008, 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 $6.9 million and certificates of deposit valued at approximately $3.8 million. The Company also has a U.S. treasury bill totaling $200,710.

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, 2008, 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, 2008

	Level 1	Level 2	Level 3	Balance at December 31, 2008
Assets				
Marketable equity securities	$ $22,000	$ —	$ —	$ 22,000
Money market funds	6.926,612	—	—	6,926,612
Certificates of deposit	3,847,904	—	—	3,847,904
Treasury bills	200,710	—	—	200,710
Liabilities				
Derivative financial instruments	$ —	$ 448,318	$ —	$ 448,318

The Company does not have any fair value measurements using significant unobservable inputs (Level 3) as of December 31, 2008.

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(8) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2008 and 2007.

	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)	(2,825)
Derivative instrument income (expense)	198	(671)	1,281	296
Net income (loss)	(1,058)	(2,420)	(878)	(2,509)
Basic and diluted income (loss) per share	(0.04)	(0.10)	(0.03)	(0.10)

	2007 Quarters Ended			
(in thousands except per share amounts)	March 31	June 30	September 30	December 31
Net sales	$ —	$ —	$ —	$ —
Gross profit	—	—	—	—
Operating loss	(1,340)	(2,267)	(1,735)	(1.521)
Derivative instrument income (expense)	—	—	(78)	2,795
Net income (loss)	(1,274)	(2,179)	(1,712)	1,501
Basic and diluted income (loss) per share	(0.06)	(0.10)	(0.08)	0.08

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Based on an evaluation of the Company's disclosure controls and procedures performed by the Company's Chief Executive Officer and Controller as of the end of the period covered by this report, the Company's Chief Executive Officer and Controller concluded that the Company's disclosure controls and procedures have been effective.

As used herein, "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms issued by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer or officers and its principal financial officer or officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation described above that occurred during the period covered by this report that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's 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, 2008. 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, 2008, our internal control over financial reporting was effective based on those criteria.

CCR LLP ("CCR"), our Independent Registered Public Accounting Firm, audited the effectiveness of our Company's internal control over financial reporting as of December 31, 2008, and CCR's report is included under Item 8 in this Annual Report on Form 10-K.

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Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

There was no information required to be disclosed in this Annual Report on Form 10-K during the fourth quarter of the year ended December 31, 2008 that was not so reported.

PART III

Item 10. Directors, Executive Officers of the Registrant and Corporate Governance

The information required by Items 401, 405, 406, and 407(c)(3), (d)(4) and (d)(5) of Regulation S-K, regarding the Company's directors and executive officers, compliance with Section 16(a) of the Exchange Act, Code of Ethics, procedures by which security holders may recommend nominees to the Company's Board of Directors, and Audit Committee and Audit Committee Financial Expert, is incorporated by reference into this Form 10-K by reference to the Company's definitive proxy statement (the "Definitive Proxy Statement") for its 2009 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by Item 402 and paragraphs (e)(4) and (e)(5) of Item 407 of Regulation S-K, regarding executive compensation, Compensation Committee Interlocks and Insider Participation and the report of the Compensation and Stock Option Committee of the Company's Board of Directors, is incorporated into this Form 10-K by reference to the Definitive Proxy Statement.

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

The information required by Item 201(d) of Regulation S-K is included in this Form 10-K under Item 5. The information required by Item 403 of Regulation S-K, regarding the security ownership of certain beneficial owners of the Company's common stock and the Company's management, is incorporated into this Form 10-K by reference to the Definitive Proxy Statement.

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

The information required by Item 404 of Regulation S-K, regarding certain relationships and related transactions, if any, and director independence, is incorporated into this Form 10-K by reference to the Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by Item 9(e) of Schedule 14A, regarding the Company's principal accounting fees and services, is incorporated into this Form 10-K by reference to the Definitive Proxy Statement.

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PART IV

Item 15. Exhibits, and Financial Statement Schedules

1. Financial Statements: See “Financial Statements and Supplementary Data”
2. Financial Statement Schedule: See “Schedule II – Valuation and Qualifying Accounts” in this section of this Form 10-K.
3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-K.

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Delcath Systems, Inc.
Schedule II – Valuation and Qualifying Accounts
Years ended December 31, 2008, 2007 and 2006
(in millions)

		Additions		
	Balance at beginning	Charged to costs and expenses	Charged to revenue	Balance at end of period
2008				
Deferred tax asset valuation allowance	10.4	3.2	—$	13.6
2007				
Deferred tax asset valuation allowance	8.5	1.9	—$	10.4
2006				
Deferred tax asset valuation allowance	4.0	4.5	—$	8.5

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Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc., 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 Delcath Systems, Inc. (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 Delcath Systems, Inc. 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 Delcath Systems, Inc. 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)).
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	Common Stock Purchase Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. 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)).

10.5 Registration Rights Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. 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)).

10.6 Common Stock Purchase Agreement dated as of November 27, 2005 by and among Delcath Systems, Inc. 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)).

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Exhibit No.	Description
10.7	Registration Rights Agreement dated as of November 27, 2005 by and among Delcath Systems, Inc. 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)).
10.8	Voting Agreement dated as of November 27, 2005 by and between Delcath Systems, Inc., 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)).
10.9	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)).
10.10	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)).
10.11	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)).
10.12	Settlement Agreement, dated as of October 8, 2006, by and between Delcath Systems, Inc., 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)).
10.13	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)).
10.14	Settlement Agreement, dated as of December 15, 2006 between Delcath Systems, Inc. and M. S. Koly (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 21, 2006 (Commission File No. 001-16133)).
10.15	Employment Agreement dated as of July 2, 2007 between Delcath Systems, Inc. and Richard L. Taney (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 5, 2007 (Commission File No. 001-16133)).
10.16	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)).

10.17	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)).

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Exhibit No.	Description
10.18	Placement Agency Agreement dated September 18, 2007 by and among Delcath Systems, Inc., 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)).
10.19	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)).
10.20	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)).
	Escrow Agreement dated September 18, 2007 between Delcath Systems, Inc., 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)).
14	Code of Business Conduct (incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-KSB for the year ended December 31, 2003 (Commission File No. 001-16133)).
23	Consent of CCR LLP
24	Power of Attorney (included on the signature page hereto).
31.1	Certification by principal executive officer Pursuant to Rule 13a 14.
31.2	Certification by principal financial officer Pursuant to Rule 13a 14.
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 principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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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/ Richard Taney
Richard Taney
Chief Executive Officer
Dated: March 2, 2009

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below does hereby constitute and appoint Richard L. Taney as his attorney-in-fact, with full power of substitution and resubstitution for him in any and all capacities to sign any and all amendments to this report on Form 10-K of Delcath Systems, Inc. and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

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/ Richard Taney Richard Taney	Chief Executive Officer, and Director (principal executive officer)	March 2, 2009
/s/ Barbra C. Keck Barbra C. Keck	Controller (principal financial officer)	March 2, 2009
/s/ Harold S. Koplewicz Harold S. Koplewicz, M.D.	Chairman of the Board	March 2, 2009
/s/ Laura Philips Laura Philips, PhD	Director	March 2, 2009
/s/ Eamonn Hobbs Eamonn Hobbs	Director	March 2, 2009
/s/ Robert Ladd Robert Ladd	Director	March 2, 2009
/s/ Pamela Contag Pamela Contag	Director	March 2, 2009
/s/ Roger Stoll Roger Stoll	Director	March 2, 2009

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