DELCATH SYSTEMS INC
Form 10-K
March 12, 2008

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, 2007

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 $4.49 per share, was $96,009,701 as of June 29, 2007.

At March 1, 2008, the registrant had outstanding 25,259,284 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant’s Proxy Statement for its 2008 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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PART I

Item 1. Business.

General

Delcath Systems, Inc. ("we," "us," "our," "Delcath," or the "Company") was incorporated under Delaware law in 1988. We ar development stage company with a platform technology that isolates specific organs and body regions from the body's general circulatory system in order to administer high dose chemotherapy and other therapeutic agents directly to a diseased organ or body region, which we refer to as the "Delcath System". The first application being investigated for our system uses the Delcath technology to isolate the liver from the general circulatory system for the treatment of tumors of the liver. High doses of chemotherapy are delivered directly to tumors in the liver while protecting the patient from the toxicities that would normally result from systemic exposure to the administered chemotherapeutic drug. These higher doses could be potentially lethal to the patient if administered systemically. One of our trials is in the final testing stage (Phase III) to support the United States Food and Drug Administration (the "FDA") approval process. However, the Delcath System is not currently approved for marketing by the FDA, and it cannot be marketed in the United States without FDA pre-market approval. Our Phase III clinical trial is designed to secure marketing approval in the United States, and potentially in foreign markets as well for use of the Delcath System with the chemotherapy agent melphalan, for the treatment of malignant melanoma that has spread to the liver. We are also testing the Delcath System with melphalan against hepatocellular, neuroendocrine and adenocarcenoma; cancers that have spread to the liver in our Phase II clinical trials, as well as melanomas that received prior isolated hepatic perfusion. Additionally, we plan to conduct pre-clinical and clinical trials on the use of the Delcath System with other chemotherapy agents used 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 $24.0 million of those funds in research and development costs associated with development and testing of the Delcath System. Delcath maintains a website at www.Delcath.com.

Strategy

Our objectives are to establish the use of the Delcath System as the standard technique for delivering chemotherapy agents to the liver and to further develop and test the Delcath technology so that it may be used in the treatment of other liver diseases and of cancers in other parts of the body, and to generate growth, revenues and high returns for our stockholders through a strategy that includes the following elements:

- Completing clinical trials to obtain FDA pre-market approval for use of the Delcath System with melphalan to treat malignant melanoma that has spread to the liver. Our highest priority is completing the Phase III clinical trial, 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 System in the United States for use in administering melphalan in the treatment of melanoma that has spread to the liver. We are presently treating patients in trials being conducted by the National Cancer Institute (the "NCI") and will seek to add clinical centers to this trial in order to speed the completion of the trial.

- Obtaining approval to market the Delcath System in the United States for the treatment of additional cancers in the liver. We are testing our system in the treatment of other cancers of the liver such as primary liver cancer, and tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver as well as melanomas that received prior isolated hepatic perfusion using the drug melphalan. In 2004, we commenced Phase II studies of these three cancers in the liver and are currently recruiting and treating patients within this trial.

- Testing drugs other than melphalan, including the chemotherapeutic drug doxorubicin against primary liver cancer and oxaliplatin against metastatic colorectal tumors in the liver. We will also continue to evaluate other promising drug candidates to use with our system to treat other specific tumors in the liver.

- Explore other regional therapy applications for the Delcath System. We are evaluating other organs and procedures that may be well suited for the use of our technology. Other organs or body regions that may be evaluated for compatibility with our catheter technology include limbs, lungs, pancreas, and kidneys.

- Investigating treatment of hepatitis using anti-viral drugs. In addition to researching the use of other chemotherapy agents with the Delcath System to treat a variety of cancers, we plan to research the use of other compounds with the Delcath System to treat other diseases of the liver including hepatitis.

- Developing strategic alliances with a number of cancer centers. To this end, we are presently contacting recognized leading institutions and liver transplant centers that treat a large number of liver cancer or hepatitis patients. By working together with these institutions we intend to explore new applications for our technology and to help in the design and expansion of our clinical trials.

- Improving our technology. We will continue to identify improvements which increase potential drug dosing, simplify the procedure, shorten recovery times and expand the uses of the Delcath System. These changes may include new catheter designs, system architectures and the development of filters with specific affinity to newer anticancer and antiviral agents.

- Introducing the Delcath System into foreign markets. We may seek to establish strategic relationships with domestic and foreign firms that have an established presence or experience in the foreign markets that we intend to target. Our strategy is to focus on markets that have a high incidence of liver disease and the public or private means to provide and pay for the associated medical treatments. According to the World Health Organization, many Asian and European countries, including China, Japan, Hong Kong, the Philippines, Australia, Greece, France, Germany, Italy and Spain, have a higher incidence of hepatitis and liver cancer than the United States. We may explore arrangements with strategic partners who have experience with obtaining the necessary regulatory approvals and the marketing of medical devices in those markets.

The Cancer Treatment Market

The American Cancer Society projects that 1,437,180 new cases of cancer will be diagnosed in the United States in 2008. According to the American Cancer Society's "Cancer Facts and Figures 2008," cancer remains the second leading cause of death in the United States exceeded only by heart disease. While researchers continue to develop innovative new treatments for some forms of this disease, surgical resection, chemotherapy, radiation and hormone therapy continue to be the most commonly used treatments.

The financial burden of cancer is great for patients, their families and society. The National Institutes of Health, in the American Cancer Society's "Cancer Facts & Figures 2008," estimated the overall costs of cancer to be $219.2 billion during 2007, including $89.0 billion in 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 throughout the world. There are two forms of liver cancer: primary and metastatic. Primary liver cancer originates in the liver. Metastatic or secondary cancer in the liver results from the spread of cancer from other places in the body to the liver. In our clinical trials, we are treating patients suffering from both primary liver cancer and metastatic cancers in the liver including metastatic melanoma which has spread to 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. Delcath believes that the five-year survival rate for metastatic cancer in the liver is the same. In the liver, tumors can be surgically removed only when they are located in one of the liver's two lobes. However, since symptoms of liver cancer often do not appear until the liver tumors are distributed throughout the liver, less than 10% of primary and metastatic liver tumors can be surgically removed at the time of diagnosis. A significant number of patients surgically treated for primary and metastatic liver cancer will also experience a recurrence of their disease.

Metastatic liver cancer is characterized by microscopic cell clusters of other forms of cancer that detach from the primary site 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 or cancerous organ. When cancer cells enter the liver and develop into tumors, they tend to grow very quickly. In many cases, the patient dies not from the primary cancer, but from the tumors in the liver; the liver becomes the "life limiting organ." People cannot survive without a liver capable of performing its critical biologic functions, which include facilitating the conversion of food into energy and filtering toxic agents from the blood. The liver is one of the three most common sites to which cancer may spread. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

According to the World Health Organization (the "WHO"), primary liver cancer is the third most common form of cancer worldwide. It is estimated that there were 662,000 deaths from liver cancer throughout the world in 2005. 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. The American Cancer Society projects that in the United States there will be approximately 21,370 newly diagnosed cases of primary liver cancer in 2008 and we estimate that there will be approximately 223,000 newly diagnosed cases of metastatic cancers in the liver during the same period.

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 for males under the age of 35 years. The largest demand for effective treatment of primary hepatoma is found in Southern Europe and in Asia.

Current Liver Cancer Treatments

The prognosis for primary and secondary liver cancer patients is poor. Although limited treatment options are currently available for liver cancer, they are typically ineffective, 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, implanted infusion pumps and surgically isolated perfusion.

Resection

While surgery is considered the "gold standard" treatment option to address liver tumors, more than 90% of liver tumors are unresectable, which means they do not qualify for surgical removal. This is most often due to the following:

- Operative risk: limited liver function or poor patient health threatens survival as a result of the surgery; or
- Technical feasibility: the proximity of a cancerous tumor to a critical organ or artery or the size, location on the liver or number of tumors makes surgery not feasible.

For the patients who qualify for surgery, there are significant complications related to the procedure. Recurrence of tumors is common, and in that event, surgery typically cannot be repeated.

We believe that delivery of drugs with the Delcath System may in some cases assist in allowing a surgical option for tumors which are currently inoperable, by reducing the size and number of tumors by an amount sufficient to make resection feasible. Chemotherapy can also be administered through the Delcath 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, however, is limited by its side effects. Generally, the higher the dosage of chemotherapy administered, the greater its ability to kill cancer cells. However, due to the toxic nature of chemotherapy agents, the higher the dosage administered, the greater the damage chemotherapy agents cause to healthy tissues. As a result, the dosage of chemotherapy required to kill cancer cells can be lethal to patients.

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

The limited effectiveness of intravenous chemotherapy treatment and its debilitating, often life-threatening, side-effects makes the decision to undergo chemotherapy treatment difficult. In some instances, in an attempt to shrink tumors, a physician may prescribe a radically high-dose of chemotherapy, despite its side effects. In other cases, recognizing the inevitable result of liver cancer, the physician and patient may choose only to manage the patient's discomfort from the cancer with pain killers while foregoing treatment. While chemotherapy may be effective under laboratory conditions, the inability to provide high enough dosing to kill the cancer cells without causing death to the patient limits the agent's effectiveness.

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 positioned in the tumor, effectively freezing it. Cryosurgery involves a cycle of treatments in which the tumor is frozen, allowed to thaw and then refrozen.

While cryosurgery is considered to be relatively effective, we believe adoption of this procedure has been limited because:

- It is not an option for patients who cannot tolerate a surgical procedure;
- It involves significant complications which are similar to other surgical procedures, as well as liver fracture and hemorrhaging caused by the cycle of freezing and thawing; and
- It is associated with mortality rates estimated to be between one and five percent.

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 ineffective on large tumors. In order to perform this treatment, tumors must be well vascularized. Unfortunately, many tumors have poor vascularity which prevents effective treatment with this method. Patients are required to receive multiple treatments, making this option unattractive for many patients. Complications 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, but radiation therapies are usually used as an adjunct to other treatments for liver cancer.

Radio Frequency Ablation

Radio Frequency Ablation uses electric current in the radio frequency range to destroy cancerous cells. The procedure utilizes an ultrasound or CT scan to guide the surgeon in directing several needles into the abdomen through small incisions. The needles are heated with an electric current once they reach the tumor - it is this process that destroys the cancerous cells. This procedure is used for patients with small, nonresectable hepatocellular tumors and sometimes for metastatic liver cancers.

Microwave Ablation

Microwave Ablation is an experimental therapy similar to Radio Frequency Ablation.

Chemoembolization

Chemoembolization involves the injection of a chemotherapeutic drug in combination with a chemical to obstruct the artery delivering blood to the liver in order to deprive the tumor of oxygen and nutrients. While chemoembolization can slow the growth of tumors, it has the disadvantage of destroying healthy liver tissue deriving blood from the obstructed arteries.

Hepatic Artery Infusion

Hepatic artery infusion involves the injection of chemotherapeutic drugs directly into the artery supplying 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 does not enable physicians to prescribe higher doses of chemotherapy.

Implanted Infusion Pumps

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

Surgically Isolated Perfusion

To address this trade-off between the efficacy of intravenous chemotherapy treatment and its dire side effects, physicians have experimented with techniques to isolate the liver from the general circulatory system and to achieve a targeted delivery of chemotherapy agents to the liver. In the 1980's, a physician in Germany published a major surgical procedure in which he surgically clamped the arteries and veins supplying the liver and diverted the blood flow from the liver while infusing high dosages of chemotherapy agents 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 untoward effects on healthy areas of the body, but the treatment was not embraced by the broad medical community because it is highly invasive, resulting in prolonged recovery times, long hospital stays and very high costs. Despite improvements in the surgical treatment, it remains a major operative procedure and can only be performed at highly specialized liver cancer centers. Other physicians have experimented with the targeted delivery of chemotherapy agents to the liver by catheter, attempting to use one or more catheters to deliver and then remove those chemotherapy agents before they enter the general circulatory system. We are unaware of any non-surgical system, however, which can administer the higher drug doses made possible with the Delcath System.

Other Methods of Treatment

The FDA recently approved an oral treatment for liver cancer. 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, and many are not repeatable or have dose limiting side-effects. Treatment with these therapies is not expected to preclude subsequent treatment with the Delcath System.

Treatment with the Delcath System

The Delcath System is designed to address the critical shortcomings of conventional intravenous chemotherapy for the treatment of various cancers. The Delcath System for the treatment of liver cancer isolates the liver from the general circulatory system by blocking and diverting the flow of blood exiting the liver. This isolation permits the treatment of the diseased liver with high doses of chemotherapeutic agents, returning the blood exiting the liver to the general circulatory system only after the chemotherapy agent has been substantially removed from the blood by filtration outside the body. Based on human clinical data, we believe that the protection from the side-effects of chemotherapy to other parts of the body that is provided by the Delcath System allows for higher chemotherapy doses to be delivered to the liver than can be administered by conventional intravenous delivery. By filtering out a substantial portion of the chemotherapy agent before the blood is returned to the blood stream and the body, other organs of the body and healthy tissue receive less exposure to the chemotherapy agent. Therefore, these healthy tissues and organs are less likely to suffer from the harmful side-effects of chemotherapy. By providing higher dosing of the chemotherapy agent than would otherwise be possible via conventional chemotherapy, the treatment generates a higher number of killed cancer cells and may disable the ability of the surviving cancer cells to develop metabolic mechanisms that circumvent the killing effects.

The Delcath 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 the blood flow from the liver. These balloons are separated by fenestrations in the catheter which 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 incorporating the disposable components used with a non-disposable blood pump to push the isolated blood through the System's filter 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 being reintroduced 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 one of the major veins returning blood to the right atrium of the heart.
- 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 through one of the smaller passageways. Blood flows out of the liver through the large passageway to the filtration system. A separate access port attaches to the large passageway and is designed for sampling fluid or flushing the system. The third smaller passageway allows blood exiting the legs and kidneys to bypass the isolated segment of the body and return to the heart.

The Delcath procedure 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 and local anesthesia at catheter insertion sites. In most cases to date general anesthesia has been used. An infusion catheter is positioned in the artery through which blood normally flows 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.

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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. A chemotherapy agent is then infused into the liver through the infusion catheter. The infused blood is prevented from flowing to the heart, and instead, exits the liver through fenestrations on the double balloon catheter and flows through this catheter out of the body where the blood is pumped through activated charcoal filters to remove most of the chemotherapy agent. The filtered blood is returned into the patient through the jugular vein which leads to the superior vena cava, another major vessel of the heart, thus restoring the cleansed blood to normal circulation. In the clinical trials, infusion is administered over a period of thirty minutes. Filtration occurs during infusion and for thirty minutes afterward. The catheters are removed and manual pressure is maintained on the catheter puncture sites for approximately fifteen minutes. The entire procedure takes approximately two to three hours to administer.

During our clinical trials, patients remain in the hospital overnight for observation after undergoing treatment with the Delcath 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 System is that the procedure is repeatable and we expect a patient to undergo an average of four treatments, one every few weeks. A new Delcath 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 at NCI 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 treatment or to receive “Best Available Care” in the control arm of the trial. The primary efficacy endpoint for the trial is 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 (free from progression). Under the SPA Agreement, a patient treated in the clinical trial as part of the non-Delcath control group who thereafter experiences tumor progression will have met the primary clinical endpoint and at the Principal Investigator’s judgment can be crossed over and treated using the Delcath System. Patients are currently being treated at NCI and additional sites are expected to be added to the trial during 2008.

We intend to complete the Phase III clinical trial with melphalan designed to demonstrate to the FDA that administering this agent with the Delcath System to treat malignant melanoma that has spread to the liver results in better patient treatment outcomes than those obtained from other available treatments. Phase III clinical trials are a prerequisite for FDA approval of Delcath’s pre-market application. During these trials, administration of melphalan through the Delcath System must be proven to be safe and effective for the treatment of melanoma in the liver. The FDA requires us to demonstrate that delivering melphalan using the Delcath System results in tumor responses that are better than those obtained in the control arm.

The FDA pre-market approval we are currently seeking is limited to administration of melphalan with the Delcath System to treat patients suffering from metastatic melanoma which has spread to the liver. If we are granted this approval, we plan to seek additional FDA pre-market approvals for using the Delcath System with other chemotherapy agents for treatment of other liver cancers. In many instances, 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 for some medical devices or drug delivery systems. If we fail to raise the additional capital required or 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.

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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 and investigational new drug 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. Test subjects had primary liver cancer or cancer which had spread to the liver. Subjects were treated with melphalan, doxorubicin or 5-FU. These trials demonstrated that the Delcath System was capable of extracting up to 85% of the chemotherapy agent administered to the liver. These trials indicated that with three different anticancer agents, the Delcath System permits the delivery of higher dosages to the cancer site while at the same time minimizing the exposure of healthy tissue and organs to the effects of chemotherapeutic agents.

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

- more chemotherapy agent to the tumor site;
- less chemotherapy agent to the general circulation than that which would be delivered by administration of the same dose by intravenous means; and
- high dosing without inflicting the systemic damage that the patient would have experienced if he had received similar dosing using conventional intravenous chemotherapy administration.

In addition, clinicians involved in the Phase I and Phase II clinical trials observed reductions in tumor size.

Further, though not demonstrated in a statistically significant manner because of the limited number of patients tested, clinicians observed responses including survival times of patients treated with the Delcath System which exceeded those that would generally be expected in patients receiving chemotherapy treatment through conventional intravenous means of delivery.

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

Our Clinical Trial and Agreement with the National Cancer Institute

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 System, to patients with metastatic and unresectable cancer of the liver. The NCI was treating patients with an invasive surgical procedure called Isolated Hepatic Perfusion ("IHP"); the results of IHP were promising, but the treatment was limited because it was too invasive for sicker patients and could not be repeated, and after a period of time disease frequently recurred.

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 and a Phase III study treating patients with melanoma metastatic to the liver. 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 June 26, 2007, we announced the expansion of our Phase II multi-histology clinical trial to include a fourth arm consisting of patients with metastatic melanoma in the liver who have previously received isolated hepatic perfusion, but whose cancer has since relapsed or patients that have completed the maximum six Delcath treatments allowed in the Phase III protocol. The added arm of the trial, which is independent of the other arms, allows us to assess the impact of PHP therapy on patients who previously responded to high-dose melphalan, but later experienced a relapse with one or more tumors growing back. Patients who previously responded to the therapy are considered good candidates to respond again, and patients with prior PHP or IHP treatment in the Phase I trial had additional responses and prolonged survival times.

On March 29, 2007, following the completion of the five-year term of the CRADA between Delcath and the NCI, Delcath announced 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 System device to deliver high-dose melphalan to patients, and to evaluate the advisability of developing additional commercial agents for use with the Delcath System. Under the agreement, the Surgery Branch of the NCI will work towards completion of Delcath System's pivotal ongoing Phase III trial for patients with metastatic melanoma in the liver using the drug melphalan, and serve as the coordinating center for the multi-center trial, which is approved for expansion to a maximum of 15 centers by the FDA. Expansion to include additional clinical centers was also approved by the NCI Institutional Review Board on May 30, 2007.

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 according to the WHO. The WHO estimates 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, according to the WHO figures. The Center for Disease Control (the "CDC") estimated there were 185,000 cases of hepatitis B and 38,000 cases of hepatitis C in the U.S. in 1997. According to the CDC, Over 5,000 Americans die from hepatitis B and over 10,000 Americans die from hepatitis C every year. 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 are currently discussing the initiation of clinical trials to determine the feasibility of using the Delcath System to administer 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 of the effect of high dose antiviral therapy delivered into the liver.

Other Organs and Body Regions

Other areas of future treatment 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.

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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 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, as well as key foreign institutions. We will focus these 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.

Upon diagnosis of cancer, a patient is usually referred to a medical oncologist. Depending upon the type, size and spread of tumors in the patient, this physician generally provides palliative treatments (non-curative) and refers the patient to a surgical oncologist if surgery appears to be an option. Both medical and surgical oncologists will be included in our target market. Generally, medical oncologists do not position catheters. This is done either by an interventional radiologist or a surgeon.

We plan to hire a marketing director at such time as we receive an indication from the FDA that approval of the Delcath System is forthcoming. If we decide to market the Delcath System ourselves, we would then hire a sales manager and a small force of sales representatives to market the system in the United States.

In addition, if we can establish foreign testing and marketing relationships, we plan to utilize one or more corporate partners to market products outside the United States. We believe distribution or corporate partnering arrangements will be cost effective, can be implemented more quickly than a direct sales force established by us in such countries and will enable us to capitalize on local marketing expertise in the countries we target.

Since we plan to sell the Delcath 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 System will depend upon:

- the ability of our clinical trials to demonstrate a measurable tumor reduction in patients whose tumors would not be expected to shrink from systemic chemotherapy;
- our ability to educate physicians on the use of the system and its benefits compared to other treatment alternatives; and
- our ability to convince healthcare payers that use of the Delcath system results in reduced treatment costs of patients.

This will require substantial efforts and expenditures.

Third-Party Reimbursement

Because the Delcath System is characterized by the FDA as an experimental device, its use is not now reimbursable in the United States. We will not seek to have third-party payers, such as Medicare, Medicaid and private health insurance plans, reimburse the cost of the Delcath System until after its use is approved by the FDA.

We will identify a medical reimbursement expert to assist us in having the Delcath treatment approved for reimbursement by third party payors.

Manufacturing

We plan to continue to utilize contract manufacturers to manufacture the components of the Delcath System. The Delcath System kit is being manufactured domestically by the OEM division of B. Braun Medical, Inc. of Germany. B. Braun is also supplying the other catheters and catheter accessories. The Delcath System kit components must be manufactured and sterilized in accordance with manufacturing and performance specifications that are on file with the FDA. B. Braun has demonstrated that the components it manufactures meet these specifications. B. Braun's manufacturing facility is ISO 9000 approved, which will allow the use of the system in 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. Medtronic is a manufacturer of components used for extracorporeal blood circulation during cardiac surgery. 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") approved by the FDA and must comply with manufacturing and performance specifications for the Delcath System that are on file with the FDA. Medtronic has demonstrated that the components it manufactures meet these specifications. Medtronic's manufacturing facility is also ISO 9000 approved and, thus, the components it manufactures may be used in European markets.

The Company currently relies on a domestic supplier for the activated charcoal filters used in the Delcath System. These activated charcoal filters were previously marketed in the U. S. and overseas for blood detoxification, but their use within the Delcath system is considered experimental under Delcath's IDE approved by the FDA. Delcath is collaborating with this and other filter manufacturers to develop improved filters for use within the Delcath System.

Competition

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

The Delcath System competes with all forms of liver cancer treatments that are alternatives to resection including liver transplant, chemotherapy, cryosurgery, percutaneous ethanol injection, 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 other 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 our chances to achieve 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 System is regulated in the United States as a drug delivery system by the FDA under the Federal Food, Drug and Cosmetic Act. As such, it requires approval by the FDA of a pre-market application prior to commercial distribution.

Melphalan, the drug that we are initially seeking to have approved for delivery by the Delcath System, is a widely used chemotherapy agent that has been approved by the FDA. Like all approved drugs, the approved labeling includes indications for use, method of action, dosing, side-effects and contraindications. Because the Delcath System delivers the drug through a mode of administration and at a dose strength that differs from those currently approved, approval for revised labeling of melphalan permitting its use with the Delcath System must be obtained. The clinical trials are designed to provide the data to support this labeling change.

Under the Federal Food, Drug and Cosmetic Act, the FDA regulates the pre-clinical and clinical testing, design, manufacture, labeling, distribution, sales, marketing, post-marketing reporting, advertising and promotion of medical devices and drugs in the United States. Noncompliance with applicable requirements could result in different sanctions such as: suspension or withdrawal of clearances or approvals; total or partial suspension of production, distribution, sales and marketing; fines; injunctions; civil penalties; recall or seizure of products; and criminal prosecution of a company and its officers and employees.

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

Medical Devices. The Delcath System is a Class III medical device. Class III medical devices are those which are subject to the most stringent regulatory controls to assure reasonable safety and effectiveness because insufficient information exists to assure safety and efficacy solely through general or special controls such as labeling requirements, mandatory performance standards and post-market surveillance. As such, FDA pre-market approval is required for Class III medical devices. An application for pre-market approval must be supported by data concerning the device and its components, including the manufacturing and labeling of the device and the results of animal and laboratory testing and human clinical trials. The conduct of Phase III clinical trials is subject to regulations and to continuing oversight by institutional review boards at hospitals and research centers that conduct the trials and by the FDA. These regulations include required reporting of adverse events from use of the device during the trials. Under the Federal Food, Drug, and Cosmetic Act, clinical studies for “significant risk” Class III devices require obtaining approval by institutional review boards and the filing with the FDA of an investigational device exemption at least thirty days before initiation of the studies. Before commencing clinical trials, we obtained an investigational device exemption 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 System, by the institutional review boards at the sites where the trials were conducted.

Given the short life expectancy of patients suffering from metastatic melanoma of the liver, we believe that the FDA will review our pre-market application expeditiously. However, approval of the Delcath System may take longer if the FDA requests substantial additional information or clarification, or if any major amendments to the application are required to be filed. In addition, the FDA may refer this matter to an advisory committee of experts to obtain views about the Delcath System. This process is referred to as a "panel review," and could delay the approval of the Delcath System. The FDA will usually inspect the applicant's manufacturing facility to ensure compliance with quality systems regulations prior to approval of an application. The FDA also may conduct bio-research monitoring inspections of the clinical trial sites and the applicant to ensure data integrity and that the studies were conducted in compliance with the applicable FDA regulations, including good clinical practice regulations.

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" containing a number of conditions that must be met in order to secure approval of an application. If and when those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue an order approving the application, authorizing commercial marketing of the device under specified conditions of use. If the FDA's evaluation of the application, the clinical study sites or the manufacturing facilities is not favorable, the FDA will 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 are necessary before approval, or that post-approval studies must be conducted.

The FDA's regulations require agency approval of an application supplement for changes to a device if they affect the safety and effectiveness of the device, including new indications for use; labeling changes; the use of a different facility or establishment to manufacture, process or package the device; changes in vendors supplying components for the device; changes in manufacturing methods or quality control systems; and changes in performance or design specifications. Changes in manufacturing procedures or methods may be implemented and the device distributed thirty days after the FDA is provided with notice of these changes, unless the FDA advises the pre-market approval application holder within thirty days of receipt of the notice that the notice is inadequate or that pre-approval of an application supplement is required.

Approved medical devices remain subject to extensive regulation. Advertising and promotional activities are subject to regulation by the FDA and by the Federal Trade Commission. Other applicable requirements include the FDA's medical device reporting regulations, which require that we provide information to the FDA on deaths or serious injuries that may have been caused or contributed to by the use of marketed devices, as well as product malfunctions that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If safety or efficacy problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing or promoting of devices or drugs for indications or uses that have not been cleared or approved by the FDA. Further, the Food, Drug and Cosmetic Act authorizes the FDA to impose post-market surveillance requirements with respect to a Class III device which is reasonably likely to have a serious adverse health consequence or which is intended to be implanted in the human body for more than one year or to be a life sustaining or life supporting device used outside a hospital or ambulatory treatment center.

The Food, Drug and Cosmetic Act regulates a device manufacturer's design control, quality control and manufacturing procedures by requiring the manufacturer to demonstrate and maintain compliance with quality systems regulations including good manufacturing practices and other requirements. These regulations require, among other things, that:

- design controls, covering initial design and design changes be in place;

- the manufacturing process be regulated, controlled and documented by the use of written procedures; and

- the ability to produce devices which meet the manufacturer's specifications be validated by extensive and detailed testing of every aspect of the process.

The FDA monitors compliance with quality systems regulations, including good manufacturing practice requirements, by conducting periodic inspections of manufacturing facilities. If violations of the applicable regulations are found during FDA inspections, the FDA will notify the manufacturer of such violations and the FDA, administratively or through court enforcement action, can prohibit further manufacturing, distribution, sales and marketing of the device until the violations are cured. If violations are not cured within a reasonable length of time after the FDA provides notification of such violations, the FDA is authorized to withdraw approval of the pre-marketing approval application.

Investigational devices that require FDA pre-marketing approval in the United States but have not received such approval may be exported to countries belonging to the European Union, European Economic Area and some other specified countries, provided that the device is intended for investigational use in accordance with the laws of the importing country, has been manufactured in accordance with the FDA's good manufacturing practices or ISO standards, is labeled on the outside of the shipping carton "for export only," is not sold or offered for sale in the United States and complies with the specifications of the foreign purchaser. The export of an investigational device for investigational use to any other country requires prior authorization from the FDA. An investigational device may be exported for commercial use only as described below, under "Foreign Regulation."

Drugs. A manufacturer of a chemotherapy agent must obtain an amendment or a supplemental new drug application for a chemotherapy product providing for its use with the Delcath System before the Delcath System may be marketed in the United States to deliver that agent to the liver or any other site. The FDA-approved labeling for melphalan does not provide for its delivery with the Delcath System. It may be necessary to partner with the holder of an approved drug application for melphalan to make this change to the labeling of the agent. We have no assurance that we will reach agreement with a company or that the FDA will approve the application. If this approval is obtained, it would not have a negative effect on the manufacturer of melphalan. Rather, the drug manufacturer would have the opportunity to expand the use of the drug as a result of changing their label to include the Delcath labeling.

A Phase III clinical trial protocol using melphalan has been approved by the FDA under our investigational new drug application. FDA regulations also require that prior to initiating the trials the sponsor of the trials obtain institutional review board ("IRB") approval from each investigational site that will conduct the trials. We have received IRB approval from NCI and will seek the approval of institutional review boards at additional medical centers by assembling and providing them with information with respect to the trial.

The approved Phase III clinical trial protocol 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 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 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.

Foreign Regulation. In order for any foreign strategic partner to market our products in Asia, Europe, Latin America and other foreign jurisdictions, they must obtain required regulatory approvals or clearances and otherwise comply with extensive regulations regarding safety and manufacturing processes and quality in the respective country. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. In addition, there may be foreign regulatory barriers other than pre-market approval or clearance.

In April 1996, legislation was enacted that permits a medical device which requires FDA pre-market approval but which has not received such approval to be exported to any country for commercial use, provided that the device:

- complies with the laws of that country;
- has valid marketing authorization or the equivalent from the appropriate authority in any of a list of industrialized countries including Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa and countries in the European Economic Union; and
- meets other regulatory requirements regarding labeling, compliance with the FDA's good manufacturing practices or ISO manufacturing standards, and notification to the FDA.

In order for us to market and sell the Delcath System in foreign jurisdictions, we must obtain required regulatory approvals or clearances and otherwise comply with extensive 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 development and regulatory approval to the marketplace, the health care industry has traditionally placed considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. We hold the following eight 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:

Summary Description of Patents	**Patent No.**	**Expiration Date**
Isolated perfusion method for cancer treatment	U.S. #5,069,662	December 3, 2008
Isolated perfusion device — catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479	May 2, 2012
Device and method for isolated pelvic perfusion	U.S. #5,817,046	July 14, 2017
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841	August 30, 2016
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163	July 14, 2017
Isolated perfusion method for kidney cancer	U.S. #6,186,146	January 13, 2017
Catheter flow and lateral movement controller	U.S. #5,897,533	September 2, 2017
Method for treating glandular diseases and malignancies	U.S. #7,022,097	May 9, 2023

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

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, 2007 we had six full-time employees. We 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 at 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. You may call the Commission at 1-800-SEC-0330 for more information about the operation of the public reference room.

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 System, or if we are unable to market and sell the product, we will not generate operating revenue or become profitable.

The Delcath System, an enabling technology for the isolation of various organs in the body to permit the delivery of otherwise unacceptably toxic doses of drugs, is our only product, and our entire focus has been the development and commercialization of this product. If the Delcath 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, 2007, we have incurred cumulative net losses of approximately $39.0 million which were principally incurred in connection with our product development efforts and, in 2006, legal expenses. For the years ended December 31, 2006 and 2007, we incurred net losses of approximately $11.0 million and $3.7 million, respectively.

In the past, 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 2 to our 2007 financial statements included in this report. In addition, 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, 2007, we had cash and cash equivalents of approximately $17.8 million.

If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete the development and commercialization of our product. Additionally, as we incur additional losses, our accumulated deficit will further increase.

If we do not raise any additional capital that may be required to commercialize the Delcath System, our potential to generate future revenues will be significantly limited even if we receive FDA premarket approval.

Before we can obtain approval to sell our product commercially, we will need premarket approval from the FDA which, in turn, requires that we complete clinical trials to establish the safety and effectiveness of our System. While we have sufficient capital to conduct our operations, our current resources may not be sufficient to complete Phase III clinical trials using melphalan or other clinical trials that we may pursue and will be insufficient to fund the costs of commercializing the Delcath System, which will be significant. Many of the costs incurred in conducting clinical trials are due to uncertainties that are not within our control, including (i) the possibility that the FDA may require additional trials and the number of trials that may be required; (ii) the charges payable to each current or prospective clinical test site which may be a flat fee for a certain time period or a fee based on the number of participants in the trial; (iii) the amount of the fee per participant 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 our other costs, including the costs of retaining a clinical research organization and out of pocket costs such as travel; (vi) the actual number of treatments per patient in each clinical trial; and (vii) the possible reduction in trial costs billed to us where a patient's insurer agrees to cover treatment expenses. We do not know if additional financings will be available when needed, or if they are available, if they will be available on acceptable terms. If we are unable to obtain additional financing as needed, we will not be able to sell the Delcath System commercially.

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

As described above, while we have sufficient capital to conduct our operations, we require additional capital for research and development and for additional clinical trials. Our further liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including clinical studies; the timing and costs of making various United Sates 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 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 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 in this prospectus supplement and the accompanying prospectus contain 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 shou statements that contain these words carefully because they:

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

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

Risks Related to FDA and Foreign Regulatory Approval

Even if the FDA grants premarket approval for use of the Delcath 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 premarket approval for use of the Delcath System in the treatment of melanoma that has metastasized to the liver with 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 using 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 other drugs or to treat other diseases. The lack of separate specific approvals would limit our ability to market our product and could result in substantially reduced sales.

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

If the FDA does not approve our application for premarket approval for the Delcath System, we will not be able to export the Delcath System from the United States for marketing abroad unless approval has been obtained from one of a number of developed nations. If we do not have such approval, we will not be eligible to use a simplified registration process for the Delcath System in a number of countries including the members of the European Union, Great Britain and Australia. We have not begun to seek foreign regulatory approval and may not be able to obtain approval from one or more countries where we would like to sell the Delcath System. If we are unable to market the Delcath System internationally because we are unable to obtain required approvals, our international market opportunity will be materially limited.

Because of our limited experience, conduct of clinical trials and obtaining FDA premarket approval could be delayed.

We have experienced, and may continue to experience, delays in conducting and completing required clinical trials, caused by many factors, including our limited experience in the following areas:

- arranging for clinical trials;
- evaluating and submitting the data gathered from clinical trials;
- designing trials to conform to the trial protocols authorized by the FDA;
- complying with the requirements of institutional review boards at the sites where the trials may be conducted; and
- identifying clinical test sites and sponsoring physicians.

Completion of our clinical trials will also depend on the ability of the clinical test sites to identify patients to enroll in the clinical trials, as the population of appropriate subjects (i.e., patients with melanoma that has metastasized to the liver) is limited. The trials may also take longer to complete because of difficulties we may encounter in entering into agreements with clinical testing sites to conduct the trials. 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 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 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 launch trials overseas if the FDA were to halt the United States trials.

On October 23, 2007, we announced that we received on the afternoon of October 22, 2007, a letter from the FDA recommending that we temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal ("GI") safety concerns. The recommendation was issued by the FDA following reports of four serious adverse GI events that were submitted to the FDA, the NCI's Institutional Review Board and the Data Safety Monitoring Board, which may have been related to the infusion of melphalan. Following receipt of this letter, we decided to voluntarily defer accrual of new patients in our Phase III and Phase II trials.

During a meeting at the FDA which 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 the (GI) toxicities. These changes had been previously approved by the NCI Institutional Review Board and were subsequently approved by the Data Safety Monitoring Board for the Phase III trial. Following the meeting, we were notified in writing by the FDA that the studies can proceed with the amended protocol and we announced the notification of trial resumption in a November 20, 2007 press release.

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

- the FDA may put the Phase III and/or Phase II trials on clinical hold, meaning that they will not allow for further enrollment in and/or permanently suspend our clinical trials;
- additional serious adverse events in the clinical trials could occur;
- the Company could fail to resume enrollment in the clinical trials in a timely manner or at all; or
- other regulators or institutional review boards may not authorize, or may delay, suspend or terminate the clinical trial program due to any unresolved 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 adversely affected.

Third-party reimbursement may not be available to purchasers of the Delcath System or may be inadequate, resulting in lower sales even if FDA premarket 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 the procedures using our products from third-party payors, including Medicare, Medicaid and private health insurance plans.

The Delcath 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 not begin to seek reimbursement by third-party payors of the cost of the Delcath System until after its use is approved by the FDA. Each third-party payor independently determines whether and to what extent it will reimburse for a medical procedure or product. There are no assurances that third-party payors in the United States or abroad will agree to cover procedures using the Delcath System. Further, third-party payors may deny reimbursement if they determine that the Delcath 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.

In addition, new products are under increased scrutiny as to whether they will be covered by the various healthcare plans and as to the level of reimbursement that would be applicable to respective covered products and procedures. A third-party payor may deny reimbursement for the treatment and medical costs associated with the Delcath System, notwithstanding FDA or other regulatory approval, if that payor determines that the Delcath System is unnecessary, inappropriate, not cost effective, and experimental or is used for a non-approved indication.

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

We obtain necessary components for the Delcath System from sole-source suppliers. Because manufacturers must demonstrate compliance with FDA requirements, if our present suppliers fail to meet such requirements or if we change any supplier, the successful completion of the clinical trials and/or the commercialization of the Delcath System could be jeopardized.

We must ensure that the components of the Delcath System are manufactured in accordance with manufacturing and performance specifications of the Delcath System on file with the FDA and with drug and device good manufacturing practice requirements. Many of the components of the Delcath System are manufactured by sole source suppliers. If any of our suppliers fails to meet our needs, or if we need to seek an alternate source of supply, we may be forced to suspend or terminate our clinical trials. Further, if we need a new source of supply after commercial introduction of the Delcath System, we may face long interruptions in obtaining necessary components, which could jeopardize our ability to supply the Delcath System to the market.

Currently the Delcath System kit is being manufactured domestically by the OEM division of B. Braun Medical, Inc. of Germany which also supplies the other catheters and accessories. Medtronic USA, Inc. currently manufactures the components of the blood filtration circuit located outside of the body, including the medical tubing through which the patient's blood flows and various connectors and the blood pump head. We purchase activated charcoal filters used in the Delcath System from a single supplier.

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

We do not have any contracts with suppliers for the manufacture of components for the Delcath System. Certain components are available from only a limited number of sources. To date, we have only had components of the Delcath System manufactured for us in small quantities for use in pre-clinical studies and clinical trials. We will require significantly greater quantities to commercialize the product. Notwithstanding our best efforts, we may not be able to find an alternate source 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 System could be delayed.

Because of our limited experience in marketing products and our lack of adequate personnel to market and sell products, we may not be successful in marketing and selling the Delcath System even if we receive FDA premarket approval.

We have not previously sold, marketed or distributed any products and currently do not have the personnel, resources, experience or other capabilities to market the Delcath System adequately. 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 System will depend on substantial efforts and expenditures in an area with which we have limited experience.

Market acceptance of the Delcath System will depend upon a variety of factors including whether our clinical trials demonstrate a significant reduction in the mortality rate for the kinds of cancers treated on a cost-effective basis, our ability to educate physicians on the use of the Delcath System and our ability to convince healthcare payors that use of

the Delcath System results in reduced treatment costs to patients. We have only limited experience in these areas and we may not be successful in achieving these goals. Moreover, the Delcath 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. Many doctors and hospitals are reluctant to use a new medical technology until its value has been demonstrated. As a result, the Delcath 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 System.

Competition in the cancer treatment industry, particularly in the markets for systems and devices to improve the outcome of chemotherapy treatment, is intense. The Delcath 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, especially financial and technological. In addition, some of our competitors have considerable experience in conducting clinical trials and other regulatory procedures. These competitors are developing systems and devices to improve the outcome of chemotherapy treatment for liver cancer. If these competitors develop more effective or more affordable products or treatment methods, our profitability will be substantially reduced and the Delcath 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 premarket approval, our introducing the Delcath 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 do not currently carry 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 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 and even if we prevail on the merits, we would likely incur substantial legal and related expenses. 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.

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 trading 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. In addition, the trading volume in our common stock may fluctuate and cause significant price variations to occur. 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;
- the success of our operating strategy; and
- the operating and stock price performance of other comparable companies.

Many of these factors are beyond our control, and we cannot predict their potential effects 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. In addition, the stock markets in general can experience considerable price and volume fluctuations.

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

There is a relatively limited public float of our common stock. Because of this, trades of relatively small amounts of our common stock can have a disproportionate effect on the market price for our common stock. The market price of our common stock has historically been volatile. During the three years ended December 31, 2007, 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 $0.92 (during the quarter ended December 31, 2007).

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, 2007, our executive officers, directors and affiliated persons beneficially own approximately 14.2% 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.

In addition, 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. Management's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price.

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, and certain provisions of our Certificate of Incorporation and By-laws and of our stockholders rights plan could make it more difficult for our stockholders to replace management.

Provisions of our certificate of incorporation and by-laws and our stockholders rights agreement may have the effect of discouraging, delaying or preventing a change in control of us or unsolicited acquisition proposals that a stockholder might consider favorable. 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 would favor a change in management. These include provisions:

- providing for a classified 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 which could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

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

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. On April 30, 2007, we were notified by NASDAQ that due to the resignations of two of our independent directors on April 16, 2007, we no longer complied with NASDAQ's requirements to have a majority of independent directors on our Board of Directors, and for our Audit Committee to have three members. On May 24, 2007, the Company regained compliance with both of these requirements within the cure period allowed by NASDAQ (on or before October 13, 2007). However, 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. In addition, if we fail to meet any of the other applicable criteria, 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. The additional burdens imposed upon broker-dealers by such 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

We have been involved in a legal proceeding that was originally filed on August 12, 2005 in the United States District Court, District of Connecticut against Elizabeth L. Enney (the "Defendant"). The named plaintiffs are Delcath Systems, Inc. and M.S. Koly (former CEO, President, Treasurer and Director of Delcath), individually and as a Director of Delcath Systems, Inc. (collectively, the "Plaintiffs"). The operative complaint seeks damages for libel. In May 2006, the libel claims were dismissed for lack of personal jurisdiction, and in July 2006, Plaintiffs filed a new libel claim in the United States District Court for the Northern District of Georgia. On November 1, 2006, Defendant filed a Motion for Judgment claiming that Plaintiffs' complaint and the attachments thereto, on their face, were insufficient to support Plaintiffs' libel claim as a matter of law. On December 22, 2006, Defendant filed a motion under Rule 11 of the Federal Rules of Civil Procedure seeking an order directing payment to the Defendant of reasonable attorneys' fees and expenses by Plaintiff. On April 19, 2007, the entire action was ordered and adjudged to be dismissed, and the Defendant was granted recovery of her costs, however, her motion for sanctions against the Plaintiffs was denied.

On May 21, 2007, Defendant filed an appeal to the United States Court of Appeals for the 11th Circuit from the final judgment and order of the court entered on April 19, 2007 denying Defendant's motion for sanctions against the Plaintiffs. On March 7, 2008, the Court of Appeals found that the District Court abused its discretion by denying the Defendant's motion for sanctions, and reversed the District Court's order and remanded it to the District Court for further proceedings to determine the appropriate amount of the sanctions. The Defendant has quantified the costs she claims were occasioned by this lawsuit in a separate action (in which we are not a party) at $450,000, an amount we would dispute vigorously if the Defendant were to claim that amount in the remanded proceedings in the District Court. However, no assurance can be given concerning the amount of the sanctions for which we may ultimately be held liable.

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

No matters were submitted to a vote of our security holders during the fourth quarter of 2007.

PART II

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

	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

	2006	
	High	**Low**
Quarter ended March 31, 2006	$ 4.90	$ 3.26
Quarter ended June 30, 2006	6.00	3.75
Quarter ended September 30, 2006	5.95	3.77
Quarter ended December 31, 2006	4.05	2.77

As of March 8, 2008, there were approximately 87 stockholders of record of our Common Stock and approximately 3,911 additional beneficial owners 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, 2002 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.

Company/Index/Market	2002	2003	2004	2005	2006	2007
Delcath Systems	100.00	55.15	182.42	206.06	224.24	112.12
Industry Group	100.00	144.90	211.83	190.78	176.47	192.67
NASDAQ Market Index	100.00	150.36	163.00	166.58	183.68	201.91

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2007 with respect to our compensation plans under which our equity securities are authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options, and rights (a)	Weighted average exercise price of outstanding options, and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[(1)]	1,140,000	$ 4.54	847,500
Equity compensation plans not approved by security holders	-	-	-
Total	1,140,000	$ 4.54	847,500

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

Additional Information

We did not sell any equity securities during our 2007 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 2007 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, 2007, are derived from the financial statements of Delcath Systems, Inc. The financial statements as of December 31, 2007 and 2006 and for each of the three-year period ended December 31, 2007 (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."

(Dollars in thousands)	Years Ended December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
Statement of Operations Data					
Costs and expenses	$ 6,913	$ 11,699	$ 3,112	$ 3,367	$ 2,306
Operating loss	6,913	11,699	3,112	3,367	2,306
Net Loss	3,664	10,952	2,865	3,266	2,250

	Years Ended December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
Balance Sheet Data					
Current assets	$ 18,091	$ 8,760	$ 12,920	$ 7,338	$ 2,393
Total assets	18,106	8,764	12,928	7,352	2,430
Current liabilities	1,677	670	330	565	260
Stockholder’s equity	16,428	8,093	12,598	6,787	2,170

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

Since our founding in 1988 by a team of physicians, we have been a development stage company engaged primarily in developing and testing the Delcath System for the treatment of liver cancer. A substantial portion of our historical expenses have been for the development of our medical device and the clinical trials of our product, and the pursuit of patents worldwide, as described in Item 1 under “Patents, Trade Secrets and Proprietary Rights.” We expect to continue to incur significant losses from costs for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishment of a sales and marketing organization without any significant revenues. A detailed description of the cash used to fund historical operations is included in the financial statements and the notes thereto included elsewhere in this report. Without an FDA-approved product and commercial sales, we will continue to be dependent upon existing cash and the sale of equity or debt to fund future activities. While the amount of future net losses and time required to reach profitability are uncertain, our ability to generate significant revenue and become profitable will depend on our success in commercializing our device.

During 2001, Delcath initiated the clinical trial of the Delcath System for isolated liver perfusion using the chemotherapeutic agent, melphalan. Enrollment of new patients in the Phase I trial was completed in 2003.

In 2004, we commenced a Phase II clinical trial protocol for the study of the Delcath System for inoperable primary liver cancer and adenocarcinomas and neuroendocrine cancers that have metastazed to the liver using melphalan.

In 2006, we started enrolling and treating patients in a pivotal Phase III trial for the study of the Delcath System for inoperable melanoma in the liver using melphalan under the FDA’s Fast Track and SPA approved protocol.

On October 23, 2007, we announced that we received on the afternoon of October 22, 2007, a letter from the FDA recommending that we temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal (“GI”) safety concerns. The recommendation was issued by the FDA following reports of four serious adverse GI events that were submitted to the FDA, the NCI Institutional

Review Board and the Data Safety Monitoring Board, which may have been related to the infusion of melphalan. Following receipt of this letter, we decided to voluntarily defer accrual of new patients in our Phase III and Phase II trials.

During a meeting at the FDA which 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 the (GI) toxicities. These changes had been previously approved by the NCI Institutional Review Board and were subsequently approved by the Data Safety Monitoring Board for the Phase III trial. Following the meeting, we were notified in writing by the FDA that the studies can proceed with the amended protocol, and we announced the notification of trial resumption in a November 20, 2007 press release.

Over the next 12 months, we expect to continue to incur substantial expenses related to the research and development of our technology, including Phase III and Phase II clinical trials clinical trials using melphalan with the Delcath System. Additional funds, when available, will be committed to pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath System for the treatment of liver cancer, and the development of additional products and components. We will also continue efforts to qualify additional sources of the key components of our device, in an effort to further reduce manufacturing costs and minimize dependency on a single source of supply.

Liquidity and Capital Resources

At December 31, 2007, we had cash, cash equivalents and certificates of deposit of $17,765,637, as compared to $8,698,025 at December 31, 2006 and $12,893,495 at December 31, 2005. Because money market rates have been equal to or greater than what we could receive in CDs, nearly all of our funds are currently invested in money market accounts which are shown in our financial statements as part of “Cash and Cash Equivalents.”

During the year ended December 31, 2007, we used $5,569,197 of cash in our operating activities. This amount compares to $9,202,451 used in our operating activities during the year ended December 31, 2006 and $3,019,217 during the year ended December 31, 2005. The substantial difference in cash used in operating activities between 2005 and 2006 was primarily due to the legal costs incurred in resolving various legal issues during 2006. Our cash used in operating activities in 2007 returned to a more consistent basis other than the final costs related to the 2006 legal issues and an increase in research and development costs in order to speed the FDA approval of the Delcath System.

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 various sales of securities described in Note 2 to our 2007 financial statements included in this report. In addition, 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 the registered direct offering of our common stock and warrants we completed in September 2007.

Although there can be no assurances, management believes that, as of December 31, 2007, the Company has sufficient capital to complete our existing Phase II and Phase III clinical trials. We expect our available funds to be sufficient for our anticipated needs for working capital and capital expenditures through 2008 provided no studies using new agents or treating new organs are initiated outside of the Cooperative Research and Development Agreement (“CRADA”) with the National Cancer Institute (“NCI”). The Phase III trials which are underway at NCI received Fast Track designation from the FDA and the trial is being conducted under a Special Protocol Assessment (“SPA”). We will be expanding this trial to multiple centers to accelerate enrollment and increase awareness. We are not projecting any capital

expenditures that will significantly affect our liquidity during the next 12 months. However, our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including clinical studies; 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.

Off-Balance Sheet Arrangements

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 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 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 at least the next twelve months, but anticipate that we may require additional working capital after fiscal 2008. 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, 2007; Comparisons of Results of the Years Ended December 31, 2006 and 2005

We have operated at a loss for our entire history. 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 our sale of common stock and warrants 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 resulted in the recording of derivative income for the year of $2,717,000 which substantially reduced the net loss from continuing operations.

Our net loss for the twelve months ended December 31, 2006 was $10,951,606, which is $8,086,987, or 282.3%, higher than the net loss from continuing operations for the same period in 2005. This is primarily due to the extraordinary costs incurred in 2006 in resolving various legal issues concerning the continuing management of Delcath discussed further above.

General and Administrative Expenses

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 the current period 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 operations 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 operations during 2007.

During the prior year, general and administrative expenses had increased by 556.8% from $1,367,344 during the twelve months ended December 31, 2005, to $8,980,424 for the twelve months ended December 31, 2006. This increase was primarily caused by the extraordinary legal and related costs incurred in 2006 along with the recognition of stock option costs in 2006 in accordance with the adoption of SFAS 123R (See *Note* (*e*) *Stock Option Plan* in the Notes to the Financial Statements included in this report).

Research and Development Expenses

During the twelve months ended December 31, 2007, we incurred $4,241,517 in research and development costs, which is a 56.1% increase as compared to $2,718,084 of research and development costs during 2006. This increase is primarily due to increased expenses with the NCI, as discussed above, as well as accelerated clinical development costs relating to all facets of the Delcath System which has required greater expense but will hasten the progress toward final approval. In addition, a portion of the share-based compensation for options discussed above is allocated to research and development

During the twelve months ended December 31, 2006, we incurred an increase in research and development costs of $973,843, which was a 55.8% increase compared to $1,744,251 of research and development costs during the same period in 2005. This was primarily caused by an increase in consultant costs along with an allocation of stock option costs in accordance with SFAS 123R as explained above.

Interest Income

Interest income shown is from our money market accounts and certificate of deposit (“CD”) investments. During the twelve months ended December 31, 2007, we had interest income of $532,793, as compared to interest income of $620,403, or a 14% change, for the same period in 2006. This decrease is primarily due to a reduced cash position in 2007 from that in 2006. The net proceeds from the sale of our 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.

Interest income in 2006 increased by $373,427, or 151.2%, from $246,976 in 2005. This was the result of the receipt of additional funds and the investment of such funds from a private placement of our common stock at the end of 2005, along with the exercise of outstanding warrants and options during 2006.

Forward Looking Statements

Certain statements in this Form 10-K, including statements of our and management's expectations, intentions, plans, objectives and beliefs, including those contained in or implied by "Management's Discussion and Analysis or Plan of Operation," are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and that are subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans," "wil "may," and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expansion and possible results from expansion, our expected growth, our capital budget and future capital requirements, the availability of funds and our ability to meet future capital needs, the realization of our deferred tax assets, and the assumptions described in this report underlying such forward-looking statements. Actual results and developments could differ materially from those expressed in or implied by such statements due to a number of factors, including without limitation, those described in the context of such forward-looking statements, our expansion strategy, our ability to achieve operating efficiencies, industry pricing and technology trends, evolving industry standards, domestic and international regulatory matters, general economic and business conditions, the strength and financial resources of our competitors, our ability to find and retain skilled personnel, the political and economic climate in which we conduct operations, the risks discussed in Item 1 above under "Description of Business" and other risk factors described from time to time in our other documents and reports filed with the Commission. We do not assume any responsibility to publicly update any of our forward-looking statements regardless of whether factors change as a result of new information, future events or for any other reason. We advise you to review any additional disclosures we make in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Reports on Form 10-K reports filed with the Commission.

Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 accounting principles generally accepted in the United States of America.

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

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We adopted SFAS 123(R) in 2005.

We account for derivatives embedded in contracts, such as warrants, in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock.* The accounting guidance requires that the warrants be recorded at fair value for each reporting period with mark-to-market changes in fair value recorded in the statement of operations.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

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 value of these securities.

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 year ended December 31, 2007, the Company recorded pre-tax derivative instrument income of $2,717,000. The resulting derivative instrument liability totaled $1,552,000 at December 31, 2007. 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 3.49%, volatility of 76.21% and an expected life equal to the September 24, 2012 contractual life of the warrants.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Delcath Systems, Inc. ("Company") as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007 and cumulative from inception (August 5, 1988) to December 31, 2007. We also have audited the Company's internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007 and cumulative from inception (August 5, 1988) to December 31, 2007 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, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ Carlin, Charron & Rosen, LLP

Glastonbury, CT
March 12, 2008

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Balance Sheets as of December 31, 2007 and 2006

	December 31, 2007	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 7,886,937	$ 6,289,723
Investments - treasury bills	9,878,700	-
Certificates of deposit	-	2,408,302
Prepaid expenses	325,452	61,917
Total current assets	$ 18,091,089	$ 8,759,942
Property and equipment, net	15,037	3,719
Total assets	$ 18,106,126	$ 8,763,661
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 125,278	$ 670,367
Derivative instrument liability	1,552,000	
Total current liabilities	1,677,278	670,367
Commitments (Note 4) 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	252,593	206,608
Additional paid-in capital	56,626,533	44,673,458
Deficit accumulated during development stage	(40,450,278)	(36,786,772)
Total stockholders' equity	16,428,848	8,093,294
Total liabilities and stockholders' equity	$ 18,106,126	$ 8,763,661

See Accompanying Notes to these Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Operations
for the Years Ended December 31, 2007, 2006, and 2005 and
Cumulative from Inception (August 5, 1988) to December 31, 2007

	Year ended December 31,			Cumulative from inception (August 5, 1988) To December 31,
	2007	2006	2005	2007
Costs and expenses				
General and administrative expenses	$ 2,671,782	$ 8,980,424	$ 1,367,344	$ 20,091,411
Research and development costs	4,241,517	2,718,084	1,744,251	24,019,081
Total costs and expenses	6,913,299	11,698,508	3,111,595	44,110,492
Operating loss	(6,913,299)	(11,698,508)	(3,111,595)	(44,110,492)
Derivative instrument income	2,717,000	—	—	2,717,000
Interest income	532,793	620,403	246,976	2,486,792
Other income	—	126,500	—	126,500
Interest expense	—	—	—	(171,473)
Net loss	$ (3,663,506)	$ (10,951,605)	$ (2,864,619)	$ (38,951,673)
Common share data				
Basic and diluted loss per share	$ (0.16)	$ (0.55)	$ (0.18)	
Weighted average number of basic and diluted common shares outstanding	22,321,488	19,906,932	16,038,716	

See Accompanying Notes to these Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2007, 2006, and 2005 and Cumulative from Inception (August 5, 1988) to December 31, 2007

	Common stock $.01 par value								
	Issued		In Treasury		Outstanding		Preferred Stock $0.01		
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# to
Shares issued in connection with the formation of the Company as of August 22, 1988	621,089	$ 6,211	-	$ -	621,089	$ 6,211	-	-	$
Sale of preferred stock, August 22, 1988	-	-	-	-	-	-	-	-	2
Shares returned due to relevant technology milestones not being fully achieved, March 8, 1990	-	-	(414,059)	(4,141)	(414,059)	(4,141)	-	-	
Sale of stock, October 2, 1990	-	-	17,252	173	17,252	173	-	-	
Sale of stock (common stock at $7.39 per share and Class B preferred stock at $2.55 per share), January 23, 1991	-	-	46,522	465	46,522	465	-	-	
Sale of stock, August 30, 1991	-	-	1,353	14	1,353	14	-	-	
Sale of stock, December 31, 1992	-	-	103,515	1,035	103,515	1,035	-	-	
Sale of stock (including 10,318 warrants, each to purchase one share of common stock at $10.87), July 15, 1994	-	-	103,239	1,032	103,239	1,032	-	-	
Sale of stock, December 19, 1996	-	-	39,512	395	39,512	395	-	-	
Shares issued (including 78,438 warrants each to purchase one share of common stock at $10.87) in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984	156,879	1,569	-	-	
Sale of stock, December 31, 1997	53,483	535	-	-	53,483	535	-	-	
Exercise of stock options	13,802	138	3,450	35	17,252	173	-	-	
Shares issued as compensation for consulting services valued at $10.87 per share based on a 1996 agreement	2,345	23	828	8	3,173	31	-	-	
Shares issued in connection with exercise of warrants	21,568	216	-	-	21,568	216	-	-	
Sale of stock, January 16, 1998	34,505	345	-	-	34,505	345	-	-	
Sale of stock, September 24, 1998	3,450	35	-	-	3,450	35	-	-	
Shares returned as a settlement of a dispute with a former director at $1.45 per share, the price originally paid, April 17, 1998	(3,450)	(35)	-	-	(3,450)	(35)	-	-	
Exercise of stock options	8,626	86	-	-	8,626	86	-	-	
	46,987	470	-	-	46,987	470	-	-	

Sale of stock (including 5,218 warrants each to purchase one share of common stock at $14.87), June 30, 1999									
Shares issued in connection with exercise of warrants	2,300	23	-	-	2,300	23	-	-	
Sale of stock, April 14, 2000	230,873	2,309	-	-	230,873	2,309	-	-	
Dividends paid on preferred stock	690,910	6,909	-	-	690,910	6,909	-	-	
Conversion of preferred stock	833,873	8,339	-	-	833,873	8,339	-	-	(2
Sale of stock (including 1,200,000 warrants each to purchase one share of common stock at $6.60), October 19, 2000	1,200,000	12,000	-	-	1,200,000	12,000	-	-	

See Accompanying Notes to these Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2007, 2006, and 2005 and Cumulative from Inception (August 5, 1988) to December 31, 2007

Common stock $.01 par value

	Issued		In Treasury		Outstanding		Preferred Stock $0.01 Par Value		Class A Preferred Stock $0.01 Par Value		Class B Stock $0.01 Par Value			
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	Additional Paid-in Capital	Deficit Accumulated during the development stage
Shares issued as compensation for stock sale	85,000	850	-	-	85,000	850	-	-	-	-	-	-	(850)	-
1,720 stock options (including 1,720 warrants each to purchase one share of common stock at $6.00), issued as compensation	-	-	-	-	-	-	-	-	-	-	-	-	3,800	-
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	-	-	(36)	(1)	-	-	-	-	-	-	1	-
Stock warrants (150,000 at $7.00 and 150,000 at $6.60) issued as compensation	-	-	-	-	-	-	-	-	-	-	-	-	198,000	-
Sale of stock on April 3, 2002	243,181	2,432	-	-	243,181	2,432	-	-	-	-	-	-	265,068	-
Repurchases of stock, November and December 2002			(28,100)	(281)	(28,100)	(281)	-	-	-	-	-	-	(50,822)	-
Amortization since inception of compensatory stock options	-	-	-	-	-	-	-	-	-	-	-	-	3,760,951	-
Forfeiture since inception of stock options	-	-	-	-	-	-	-	-	-	-	-	-	(1,240,780)	-
Sale of stock (including 3,895,155 warrants to purchase one share of common stock at $0.775) on May 20, 2003 including underwriter's exercise of over allotment option	3,895,155	38,952	-	-	3,895,155	38,952	-	-	-	-	-	-	1,453,696	-
Proceeds from sale of unit option	-	-	-	-	-	-	-	-	-	-	-	-	68	-
Exercise of 2003 Warrants	1,730,580	17,305	-	-	1,730,580	17,305	-	-	-	-	-	-	1,273,895	-

Sale of stock, March, 2004	1,197,032	11,970	-	-	1,197,032	11,970	-	-	-	-	-	-	2,660,625	-	2,6
Exercise of 2002 Warrants	20,265	203	-	-	20,265	203	-	-	-	-	-	-	26,547	-	
Sale of stock, April, 2004	290,457	2,905	-	-	290,457	2,905	-	-	-	-	-	-	635,130	-	6
Stock options issued as compensation	-	-	-	-	-	-	-	-	-	-	-	-	5,222	-	
Sale of stock, November, 2004	1,069,520	10,695	-	-	1,069,520	10,695	-	-	-	-	-	-	1,829,305	-	1,8
Sale of stock, December, 2004	236,966	2,370	-	-	236,966	2,370	-	-	-	-	-	-	497,630	-	5
Exercise of 2003 Warrants	2,160,163	21,602	-	-	2,160,163	21,602	-	-	-	-	-	-	1,652,524	-	1,6
Exercise of 2003 Representative's Unit Warrants	282,025	2,820	-	-	282,025	2,820	-	-	-	-	-	-	284,383	-	2
Exercise of Representative's Common Stock Warrants	152,025	1,520	-	-	152,025	1,520	-	-	-	-	-	-	193,072	-	1
Exercise of stock options	62,000	620	-	-	62,000	620	-	-	-	-	-	-	44,040	-	
Exercise of 2003 Representative's Unit Warrants	42,180	422	-	-	42,180	422	-	-	-	-	-	-	42,686	-	
Exercise of Representative's Common Stock Warrants	157,180	1,572	-	-	157,180	1,572	-	-	-	-	-	-	200,619	-	2
Exercise of stock options	597,000	5,970	-	-	597,000	5,970	-	-	-	-	-	-	525,140	-	5
Stock options issued as compensation	-	-	-	-	-	-	-	-	-	-	-	-	8,270	-	
Exercise of 2004 Warrants	1,107,313	11,073	-	-	1,107,313	11,073	-	-	-	-	-	-	2,883,418	-	2,8
Exercise of 2005 Warrants	940,957	9,410	-	-	940,957	9,410	-	-	-	-	-	-	2,573,363	-	2,5
Sale of stock, November, 2005	753,013	7,530	-	-	753,013	7,530	-	-	-	-	-	-	2,302,471	-	2,3
Shares issued as compensation	36,925	369	-	-	36,925	369	-	-	-	-	-	-	103,056	-	

See Accompanying Notes to these Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Stockholders' Equity
for the Years Ended December 31, 2007, 2006, and 2005 and Cumulative from Inception (August 5, 1988) to December 31, 2007

	Common stock $.01 par value						Class A	Class B					
	Issued		In Treasury		Outstanding		Preferred Stock $0.01 Par Value	Preferred Stock $0.01 Par Value	Preferred Stock $0.01 Par Value	Preferred Stock $0.01 Par Value	Preferred Stock $0.01 Par Value	Preferred Stock $0.01 Par Value	
	# of Shares	Amount	# of Shares	Amount	# of Shares	Amount	# of Shares	# of Shares	# of Shares	# of Shares	# of Shares	Amount	Additional Paid-in Capital
Deficit accumulated from inception to December 31, 2005	-	-	-	-	-	-	-	-	-	-	-	-	-
Balance at December 31, 2005	18,877,753	$ 188,778	(28,100)	$ (281)	18,849,653	$ 188,497	-	$ -	-	$ -	-	$ -	$ 38,244,566
Vesting of stock options	-	-	-	-	-	-	-	-	-	-	-	-	446,000
Stock options issued as compensation	-	-	-	-	-	-	-	-	-	-	-	-	505,282
Exercise of 2003 Representative's Unit Warrants	6,250	62	-	-	6,250	62	-	-	-	-	-	-	6,326
Exercise of Representative's Common Stock Warrants	6,250	63	-	-	6,250	63	-	-	-	-	-	-	7,937
Exercise of 2004 Warrants	1,165,210	11,652	-	-	1,165,210	11,652	-	-	-	-	-	-	3,306,090
Exercise of 2005 Warrants	429,218	4,292	-	-	429,218	4,292	-	-	-	-	-	-	1,557,233
Exercise of stock options	104,182	1,042	-	-	104,182	1,042	-	-	-	-	-	-	295,024
Shares issued in connection with settlement of Consent Solicitation lawsuit	100,000	1,000	-	-	100,000	1,000	-	-	-	-	-	-	305,000
Net Loss	-	-	-	-	-	-	-	-	`	-	-	-	
Balance at December 31, 2006	20,688,863	$ 206,889	(28,100)	$ (281)	20,660,763	$ 206,608	-	$ -	-	$ -	-	$ -	$ 44,673,458
Exercise of stock options	715,413	7,154	-	-	715,413	7,154	-	-	-	-	-	-	1,793,029
Shares issued as compensation	50,000	500	-	-	50,000	500	-	-	-	-	-	-	210,500
Sale of stock (including 1,916,554 warrants each to purchase one share of common stock at $4.53)	3,833,108	38,331	-	-	3,833,108	38,331	-	-	-	-	-	-	8,995,936
Compensation expense for issuance of stock options	-	-	-	-	-	-	-	-	-	-	-	-	953,610
Net Loss	-	-	-	-	-	-	-	-	-	-	-	-	-
Balance at December 31, 2007	25,287,384	$ 252,874	(28,100)	$ (281)	25,259,284	$ 252,593	-	$ -	-	$ -	-	$ -	$ 56,626,533

See Accompanying Notes to these Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Cash Flows
for the Years Ended December 31, 2007, 2006, and 2005 and
Cumulative from Inception (August 5, 1988) to December 31, 2007

	Year ended December 31,			Cumulative from inception (August 5, 1988) to December 31,
	2007	**2006**	**2005**	**2007**
Cash flows from operating activities:				
Net loss	$ (3,663,506)	$ (10,951,605)	$ (2,864,619)	$ (38,951,672)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock option compensation expense	1,404,610	1,042,448	8,270	4,980,720
Stock and warrant compensation expense issued for legal settlement and consulting services	211,000	306,000	103,425	856,711
Depreciation expense	4,323	3,835	6,052	45,901
Amortization of organization costs	—	—	—	42,165
Derivative liability fair value adjustment	(2,717,000)	—	—	(2,717,000)
Changes in assets and liabilities:				
(Increase) decrease in prepaid expenses	(263,535)	(35,000)	20,899	(325,452)
Decrease (increase) in interest receivable	—	91,574	(58,688)	—
(Decrease) increase in accounts payable and accrued expenses	(545,089)	340,297	(234,556)	125,277
Net cash used in operating activities	(5,569,197)	(9,202,451)	(3,019,217)	(35,943,349)
Cash flows from investing activities:				
Purchase of equipment or furniture and fixtures	(15,641)	—	—	(60,939)
Purchase of short-term investments	(9,878,700)	(5,424,548)	(11,097,790)	(37,370,742)
Proceeds from maturities of short-term investments	2,408,302	14,114,036	7,055,129	27,492,042
Organization costs	—	—	—	(42,165)
Net cash provided by (used in) investing activities	(7,486,039)	8,689,488	(4,042,661)	(9,981,804)
Cash flows from financing activities:				
Net proceeds from sale of stock and exercise of stock options and warrants	14,652,450	5,098,555	8,563,674	52,657,764
Repurchases of common stock	—	—	—	(51,103)
Dividends paid	—	—	—	(499,535)

Proceeds from short-term borrowings	—	—	—	1,704,964
Net cash provided by financing activities	14,652,450	5,098,555	8,563,674	53,812,090
Increase in cash and cash equivalents	1,597,214	4,585,592	1,501,796	7,886,937
Cash and cash equivalents at beginning of period	6,289,723	1,704,131	202,335	—
Cash and cash equivalents at end of period	$ 7,886,937	$ 6,289,723	$ 1,704,131	$ 7,886,937
Supplemental cash flow information:				
Cash paid for interest	$ —	$ —	$ —	$ 171,473
Supplemental non-cash activities:				
Cashless exercise of stock options	$ 451,000	$ 91,166	$ —	$ 542,166
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

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Financials Statements
for the Years Ending December 31, 2007, 2006 and 2005

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

(a) Description of Business

Delcath Systems, Inc. (the "Company") is a development stage company which was founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing and removing high dose chemotherapy agents to a diseased organ system while greatly inhibiting their entry into the general circulation system. It is hoped that the procedure will result in a meaningful treatment for cancer. In November 1989, the Company was granted an Investigational Device Exemption ("IDE") and an Investigational New Drug ("IND") status for its product by the Food and Drug Administration ("FDA"). The Company is seeking to complete clinical trials in order to obtain separate FDA pre-market approvals for the use of its delivery system using melphalan, a chemotherapeutic agent, to treat malignant melanoma that has spread to the liver.

(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 $45,804 at December 31, 2007 and $41,481 at December 31, 2006. Depreciation expense for the years ended December 31, 2007, 2006 and 2005 was $4,323, $3,835, and $6,052, 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 has 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.

(e) Stock Option Plan

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" ("SFAS 123R"). This Statement is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and its related implementation guidance. 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). Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB 25, as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant. The Company also followed the disclosure requirements of SFAS 123 as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". 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. The adoption of SFAS 123R resulted in a charge to operations of $446,000 for the year ended December 31, 2006 for options granted in November 2006.

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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.

The required adoption of SFAS No. 123R as of January 1, 2006 is expected to significantly increase compensation expense for future grants. The actual impact on future years will be dependent on a number of factors, including our stock price and the level of future grants and awards. In addition, costs related to accounting and valuation services of stock options currently outstanding in accordance with SFAS No. 123R would have been cost prohibitive to the Company if the Company had not adopted certain measures. Based on these considerations and after discussion of applicable accounting literature, the Compensation Committee of the Board of Directors approved accelerating the vesting of all unvested stock options effective January 1, 2006. The acceleration of vesting resulted in the recognition of a non cash compensation expense of $505,282 on January 1, 2006 which is included in costs and expenses in the statements of operations for 2006.

Prior to January 1, 2006, the Company accounted for stock-based compensation plans in accordance with the provisions of APB 25, as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant.

Under the modified prospective method, results for the year ended December 31, 2005 were not restated to include stock option expense. The previously disclosed pro forma effects of recognizing the estimated fair value of stock based employee compensation for the year ended December 31, 2005 are presented below.

		2005
Net loss	$	(2,864,619)
Stock-based employee compensation expense included in net loss, net of related tax effects		0
Stock-based employee compensation expense determined under the fair value based method, net of related tax effects		(133,194)
Pro forma net loss	$	(2,997,813)
Loss per share (basic and diluted):		
As reported	$	(0.18)
Pro forma		(0.19)

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The per share weighted average fair value of five-year stock options granted in July 2005 was $.58 estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average assumption of a risk free interest rate of 3.77% was based on the implied yield available on a U.S. Treasury note with a term equal to the term of the underlying options. The expected volatility of 41% was estimated based upon the historical volatility of the Company's share price.

The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The per share weighted average fair value of five-year stock options granted in November 2005 was $.66 estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average assumption of a risk free interest rate of 4.45% was based on the implied yield available on a U.S. Treasury note with a term equal to the term of the underlying options. The expected volatility of 35% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of five-year stock options granted to new members of the Board of Directors in May 2007 was $1.51 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 150,000 shares) and $.99 for those options with an exercise price equal to 150% of the common stock value at the date of grant (options for an aggregate of 200,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. All of these options vest immediately. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R. The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of five-year stock options granted to a new member of the Board of Directors in June 2007 was $1.85 for those options with an exercise price equal to the common stock value at the date of grant (options for an aggregate of 50,000 shares) and $1.22 for those options with an exercise price equal to 150% of the common stock value at the date of grant (options for an aggregate of 100,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. All of these options vest immediately. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R. The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

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The per share weighted average fair value of stock options that will vest incrementally over three years during the term of employment granted to newly hired employees in June 2007 was $1.92 for those options granted in April 2007 with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares), $1.75 for those options granted in May 2007 with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares), and $1.22 for those options granted in May 2007 with an exercise price equal to 150% of the fair value of the common stock at the date of grant (options for an aggregate of 25,000 shares), estimated on the date of acceptance using the Black-Scholes option-pricing model. The expected term was estimated to be the full three year vesting period as the Company does not have a calculable history of forfeitures by employees granted options. The weighted-average assumption of a risk free interest rate of 4.60% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of five-year stock options granted to the President and Chief Executive Officer in July 2007 was $1.89 for those options with an exercise price below the grant date common stock value (options for an aggregate of 50,000 shares) and $1.31 for those options with an exercise price greater than the grant date common stock value (options for an aggregate of 100,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. All of these options vest immediately. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R. The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of five-year stock options granted to four employees in November 2007 was $0.67 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 70,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. All of these options vest immediately. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R. The weighted-average assumption of a risk free interest rate of 4.25% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 53% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

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The per share weighted average fair value of five-year stock options granted in November 2006 was $1.31 estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date. The weighted-average assumption of a risk free interest rate of 4.69% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 60% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

(f) Net Loss per Common Share

For the years ended December 31, 2007, 2006 and 2005 potential common shares from the exercise of options and warrants 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.

(g) Recent Accounting Pronouncements

Fair Value Measurements

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("SFAS No. 157") which provides a consistent definition of fair value which focuses on exit price and prioritizes, within a measurement of fair value, the use of market-based inputs over entity-specific inputs. SFAS No. 157 requires expanded disclosures about fair value measurements and establishes a three-level hierarchy for fair value measurements based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The standard also requires that a company use its own nonperformance risk when measuring liabilities carried at fair value, including derivatives. In February 2008, the FASB approved a FASB Staff Position ("FSP") that permits companies to partially defer the effective date of SFAS No. 157 for one year for nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. The FSP did not permit companies to defer recognition and disclosure requirements for financial assets and financial liabilities or for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually. SFAS No. 157 is effective for financial assets and financial liabilities and for nonfinancial assets and nonfinancial liabilities that are remeasured at least annually for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The provisions of SFAS No. 157 will be applied prospectively. The Company intends to defer adoption of SFAS No. 157 for one year for nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. The Company is currently evaluating the effects, if any, that SFAS No. 157 may have on its financial condition and results of operations.

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Fair Value Option for Financial Assets and Financial Liabilities

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities — including an Amendment of SFAS No. 115" ("SFAS No. 159"), which permits an entity to measure certain financial assets and financial liabilities at fair value that are not currently required to be measured at fair value. Entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option may be elected on an instrument-by-instrument basis, with few exceptions. SFAS No. 159 amends previous guidance to extend the use of the fair value option to available-for-sale and held-to-maturity securities. The Statement also establishes presentation and disclosure requirements to help financial statement users understand the effect of the election. SFAS No. 159 is effective as of the beginning of the first fiscal year beginning after November 15, 2007. The Company does not expect the adoption of this standard to have a material impact on its financial condition and results of operations.

Accounting for Nonrefundable Payments for Goods or Services to Be Used in Future Research and Development Activities

In June 2007, the FASB ratified Emerging Issue Task Force ("EITF") Issue No. 07-3, "Accounting for Nonrefundable Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"), requiring that nonrefundable advance payments for future research and development activities be deferred and capitalized. Such amounts should be expensed as the related goods are delivered or the related services are performed. The Statement is effective for fiscal years beginning after December 15, 2007. Management estimates that upon adoption, this guidance will not have a material effect on the Company's financial condition and results of operations.

Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards

In June 2007, the FASB ratified EITF Issue No. 06-11, "Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards" ("EITF 06-11"), which requires entities to record to additional paid in capital the tax benefits on dividends or dividend equivalents that are charged to retained earnings for certain share-based awards. In a share-based payment arrangement, employees may receive dividends or dividend equivalents on awards of nonvested equity shares, nonvested equity share units during the vesting period, and share options until the exercise date. Generally, the payment of such dividends can be treated as deductible compensation for tax purposes. The amount of tax benefits recognized in additional paid-in capital should be included in the pool of excess tax benefits available to absorb tax deficiencies on share-based payment awards. EITF 06-11 is effective for fiscal years beginning after December 15, 2007, and interim periods within those years. Management estimates that upon adoption, this guidance will not have a material effect on the Company's financial condition and results of operations.

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Business Combinations

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS No. 141(R)") which retained the underlying concepts of SFAS No. 141 in that all business combinations are still required to be accounted for at fair value under the acquisition method of accounting but SFAS No. 141(R) changed the method of applying the acquisition method in a number of significant aspects. SFAS No. 141(R) will require that: (1) for all business combinations, the acquirer records all assets and liabilities of the acquired business, including goodwill, generally at their fair values; (2) certain contingent assets and liabilities acquired be recognized at their fair values on the acquisition date; (3) contingent consideration be recognized at its fair value on the acquisition date and, for certain arrangements, changes in fair value will be recognized in earnings until settled; (4) acquisition-related transaction and restructuring costs be expensed rather than treated as part of the cost of the acquisition and included in the amount recorded for assets acquired; (5) in step acquisitions, previous equity interests in an acquiree held prior to obtaining control be re-measured to their acquisition-date fair values, with any gain or loss recognized in earnings; and (6) when making adjustments to finalize initial accounting, companies revise any previously issued post-acquisition financial information in future financial statements to reflect any adjustments as if they had been recorded on the acquisition date. SFAS No. 141(R) is effective on a prospective basis for all business combinations for which the acquisition date is on or after the beginning of the first annual period subsequent to December 15, 2008, with the exception of the accounting for valuation allowances on deferred taxes and acquired tax contingencies. SFAS No. 141(R) amends SFAS No. 109 such that adjustments made to valuation allowances on deferred taxes and acquired tax contingencies associated with acquisitions that closed prior to the effective date of this statement should also apply the provisions of SFAS No. 141(R). This standard will be applied to all future business combinations.

(h) 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.

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(i) Cash Equivalents

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

(j) Investments

The Company's investments are recorded at fair value and consist of one United States Treasury Bill with an original maturity of six months.

(k) Reclassifications

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

(2) 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%.

In March 2004, the Company completed the sale of 1,197,032 shares of its common stock and the issuance of warrants to purchase 299,258 common shares in a private placement to institutional and accredited investors. The Company received proceeds net of issuance costs of $2,672,595 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act of 1933, as amended (the "Securities Act").

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In March 2004, proceeds of $26,750 were received as 20,265 warrants the Company issued in a private placement in 2002 were exercised.

In April 2004, the Company completed an additional private placement of 290,457 shares of common stock and an aggregate of 72,614 warrants to purchase shares of its common stock, under the same terms and conditions as those sold in March 2004 for which it received net proceeds of $638,035.

In June 2004, the stockholders approved an amendment to the Company's Certificate of Incorporation to increase the authorized number of shares of common stock from 35 million to 70 million.

In November 2004, the Company completed the sale of 1,069,520 shares of its common stock and the issuance of warrants to purchase 1,996,635 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of $1,840,000 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act.

In December 2004, the Company completed the sale of 236,966 shares of its common stock and the issuance of warrants to purchase 94,787 common shares in a private placement to an institutional and accredited investor. The Company received net proceeds of $500,000 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act.

During 2004, the Company received net proceeds of $1,674,126 as 2,160,163 of the warrants issued in 2003 were exercised and for which it has issued shares of its common stock. 1,893,658 warrants were exercised following a notice of redemption issued on October 1, 2004 in accordance with the terms of the warrant, and as of December 31, 2007, all such warrants have now been redeemed.

During 2004, the Company received net proceeds of $287,203 upon the exercise of 56,405 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the Company's 2003 public offering. This resulted in the issuance of 282,025 shares of common stock together with an equal number of Representative's Common Stock Warrants. 152,025 Representative's Common Stock Warrants were exercised with an equal number of shares of common stock being issued for which the Company received net proceeds of $194,592.

The Company received a net amount of $44,660 upon the exercise of 62,000 in stock options during the last quarter of 2004. 60,000 options were exercised at a price of $0.71 per share and 2,000 were exercised at a price of $1.03 per share.

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In November 2005, the Company completed the sale of 753,013 shares of its common stock and the issuance of warrants to purchase 711,600 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of $2,310,001 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act.

During 2005, the Company received net proceeds of $43,108 upon the exercise of 8,436 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the Company's 2003 public offering. This resulted in the issuance of 42,180 shares of common stock together with an equal number of Representative's Common Stock Warrants. 157,180 Representative's Common Stock Warrants were exercised with an equal number of shares of common stock being issued and receipt of net proceeds of $202,191.

The Company received a net amount of $531,110 upon the exercise of 597,000 in stock options during 2005. 100,000 options were exercised at a price of $0.60 per share; 60,000 were exercised at a price of $0.71 per share; 120,000 were exercised at a price of $0.85 per share; and 317,000 were exercised at a price of $1.03 per share.

In 2003, the Company issued stock options as compensation to three non-employees. The cost of these options, which is based on an annual fair value calculation based on the vesting period of each option, is being recognized annually. The cost for the years 2005 and 2004 was $8,270 and $5,222, respectively. The balance of the cost was recognized in 2006 in accordance with the acceleration of vesting as discussed in Note 1(e) of these Notes to Financial Statements.

During 2005, the Company received net proceeds of $2,894,491 when 1,069,526 of the November 2004 Warrants were exercised and 37,787 of the March 2004 Warrants were exercised for which the Company has issued shares of its common stock.

During 2005, the Company issued notice to the holders of 1,200,000 Redeemable Common Stock Purchase Warrants issued in 2000 (the "2000 Warrants") that the Company would offer to exchange on a one-for-one basis any outstanding 2000 Warrants for new warrants. The new warrants were called the 2005 Redeemable Common Stock Purchase Warrants - Series A (Expiring December 31, 2005) (the "Exchange Warrants"). 989,554 of the 2000 Warrants were exchanged for Exchange Warrants. During 2005, the Company received net proceeds of $2,582,773 as 940,957 of the Exchange Warrants were exercised following a notice of redemption issued on November 15, 2005 in accordance with the terms of the Exchange Warrants. The holders of 48,597 Exchange Warrants that remained outstanding following the redemption received the redemption price of $0.10 per Exchange Warrant. All such warrants have now been redeemed.

During 2005, the Company issued common stock to directors and certain consultants that totaled 36,925 shares that had issuance values of between $2.78 and $2.95.

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During 2006, the Company received net proceeds of $6,388 upon the exercise of 1,250 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the Company's 2003 public offering. This resulted in the issuance of 6,250 shares of common stock together with an equal number of Representative's Common Stock Warrants. 6,250 Representative's Common Stock Warrants were exercised with an equal number of shares of common stock being issued and receipt of net proceeds of $8,000.

During 2006, the Company received net proceeds of $3,317,742 as 927,115 of the November 2004 Warrants were exercised, 94,787 of the December 2004 Warrants were exercised, and 143,308 of the March 2004 Warrants were exercised for which it has issued shares of its common stock.

During 2006, the Company received net proceeds of $1,561,525 as 429,218 of the November 2005 Warrants were exercised for which it has issued shares of its 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.

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Notes to Financials Statements (cont'd)
for the Years Ending December 31, 2007, 2006 and 2005

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, 2007, the Company recorded pre-tax derivative instrument income of $2,717,000. The resulting derivative instrument liability totaled $1,552,000 at December 31, 2007. 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 3.49%, volatility of 76.21% and an expected life equal to the September 24, 2012 contractual life of the warrants.

(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 stock options, stock appreciation rights, restricted stock, and stock grants may be awarded. 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.

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Notes to Financials Statements (cont'd)
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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 2007, 2006, and 2005 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2004	1,017,020	$0.60–$3.31	$ 1.28	2.72
Granted	967,500	$2.78–$3.59	3.20	
Expired	(1,720)	$3.31	3.31	
Exercised	(597,000)	$0.60–$1.03	0.89	
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

At December 31, 2007, 2006 and 2005, options for 1,023,333, 1,465,650, and 394,300 shares, respectively, were exercisable at a weighted average exercise price of $4.52, $2.87, and $1.89 per share, respectively. The aggregate intrinsic value of options outstanding and exercisable at December 31, 2007 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 $1.85 as of December 31, 2007, which would have been received by the option holders had those option holders exercised their options as of that date.

DELCATH SYSTEMS, INC.
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Notes to Financials Statements (cont'd)
for the Years Ending December 31, 2007, 2006 and 2005

(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, 2004	4,532,748	$ 1.02-10.50	$ 4.30	2.12
Issued	711,600	$ 3.60–3.91	$ 3.75	
Exercised	(2,247,624)	$ 1.02–3.01	$ 2.55	
Expired	(825,763)	$ 2.75–10.50	$ 7.01	
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

(3) **Income Taxes**

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

	Year Ended		
	2007	**2006**	**2005**
Income taxes using U.S. federal statutory rate	$ (1,245,592)	$ (3,723,546)	$ (973,970)
State income taxes, net of federal benefit	(46,582)	(789,599)	(143,644)
Valuation allowance	1,813,480	4,483,576	1,072,032
Derivative charge	(923,780)	-	-
Expiration of net operating losses	207,061	96,959	58,257
Other	195,413	(67,390)	(12,675)
	$ –	$ –	$ –

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

	2007	2006
Deferred tax assets:		
Employee compensation accruals	$ 694,000	$ 380,000
Accrual to cash	–	243,000
Net operating losses	9,743,000	7,924,000
Total deferred tax assets	10,437,000	8,547,000
Deferred tax liability:		
Accrual to cash	78,000	–
Valuation allowance	10,359,000	8,547,000
Net deferred tax assets	$ –	$ –

As of December 31, 2007 and December 31, 2006, the Company had net operating loss carryforwards for federal income tax purposes of approximately $35,969,000 and $30,223,000, respectively. A portion of the federal amount, $13,249,000, 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). The balance of $22,720,000 is available to offset future federal taxable income which expires through 2027. As of December 31, 2007 and December 31, 2006, the Company had net operating loss carryforwards for state income tax purposes of approximately $28,742,000 and $22,450,000, respectively, which expire through 2027.

Management does not expect the Company to have taxable income in the near future and 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 $1.8 million, $4.5 million and $1.1 million in 2007, 2006, and 2005, respectively.

The Company has a tax benefit of approximately $223,000 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 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, 2001 to December 31, 2007 remain open to examination by the U.S. Internal Revenue Service and state authorities.

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

(4) Commitments

(a) Operating Lease

The Company currently occupies its new 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 $98,584 for the year ended December 31, 2007 and $87,376 for each of the years ended December 31, 2006 and 2005.

(b) Cooperative Research and Development Agreement

The Company's five year Cooperative Research and Development Agreement ("CRADA") for the development of the Delcath 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 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, $195,000, and $195,000 in expenses related to this agreement for the years ended December 31, 2007, 2006 and 2005, respectively.

(5) Contingencies

The Company has been involved in a legal proceeding that was originally filed on August 12, 2005 in the United States District Court, District of Connecticut against Elizabeth L. Enney (the "Defendant"). The named plaintiffs are Delcath Systems, Inc. and M.S. Koly (former CEO, President, Treasurer and Director of Delcath), individually and as a Director of Delcath Systems, Inc. (collectively, the "Plaintiffs"). The operative complaint seeks damages for libel. In May 2006, the libel claims were dismissed for lack of personal jurisdiction, and in July 2006, Plaintiffs filed a new libel claim in the United States District Court for the Northern District of Georgia. On November 1, 2006, Defendant filed a Motion for Judgment claiming that Plaintiffs' complaint and the attachments thereto, on their face, were insufficient to support Plaintiffs' libel claim as a matter of law. On December 22, 2006, Defendant filed a motion under Rule 11 of the Federal Rules of Civil Procedure seeking an order directing payment to the Defendant of reasonable attorneys' fees and expenses by Plaintiff. On April 19, 2007, the entire action was ordered and adjudged to be dismissed, and the Defendant was granted recovery of her costs, however, her motion for sanctions against the Plaintiffs was denied. On May 21, 2007, Defendant filed an appeal to the United States Court of Appeals for the 11th Circuit from the final judgment and order of the court entered on April 19, 2007 denying Defendant's motion for sanctions against the Plaintiffs. On March 7, 2008, the Court of Appeals found that the District Court abused its discretion by denying the Defendant's motion for sanctions, and reversed the District Court's order and remanded it to the District Court for further proceedings to determine the appropriate amount of the sanctions. The Defendant has quantified the costs she claims were occasioned by this lawsuit in a separate action (in which the Company is not a party) at $450,000, an amount the Company would dispute vigorously if the Defendant were to claim that amount in

the remanded proceedings in the District Court. Although the ultimate effect of this matter is difficult to predict, management believes that its resolution will not have a material adverse effect on the Company's financial statements.

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The Company is also 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.

(6) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2007 and 2006.

(in thousands except per share amounts)	2007 Quarters Ended			
	March 31	**June 30**	**September 30**	**December 31**
Net sales	$ 0	$ 0	$ 0	$ 0
Gross profit	0	0	0	0
Derivative instrument income (expense)	0	0	(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

(in thousands except per share amounts	2006 Quarters Ended			
	March 31	**June 30**	**September 30**	**December 31**
Net sales	$ 0	$ 0	$ 0	$ 0
Gross profit	0	0	0	0
Net income (loss)	(1,184)	(1,566)	(4,689)	(3,513)
Basic and diluted income (loss) per share	(0.06)	(0.08)	(0.23)	(0.18)

Selected Quarterly Financial Data

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2007 and 2006.

(in thousands except per share amounts)	2007 Quarters Ended			
	March 31	**June 30**	**September 30**	**December 31**
Net sales	$ 0	$ 0	$ 0	$ 0
Gross profit	0	0	0	0
Derivative instrument income (expense)	0	0	(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

(in thousands except per share amounts)	2006 Quarters Ended			
	March 31	**June 30**	**September 30**	**December 31**
Net sales	$ 0	$ 0	$ 0	$ 0
Gross profit	0	0	0	0
Net income (loss)	(1,184)	(1,566)	(4,689)	(3,513)
Basic and diluted income (loss) per share	(0.06)	(0.08)	(0.23)	(0.18)

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act) as of December 31, 2007. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2007, our disclosure controls and procedures were (1) effective in accumulating and communicating information to our management, as appropriate, to allow timely decisions regarding required disclosure (2) effective, in that that they provide reasonable assurance that information we are required to disclose in the reports that we file or submit 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 Commission's rules and forms.

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, 2007. 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, 2007, our internal control over financial reporting was effective based on those criteria.

Carlin, Charron & Rosen, LLP ("CCR"), our Independent Registered Public Accounting Firm, audited the effectiveness of our Company's internal control over financial reporting as of December 31, 2007, and CCR's report is included under Item 8 in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2007 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 a Current Report on Form 8-K during the fourth quarter of the year ended December 31, 2007 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 2008 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.

PART IV

Item 15. Exhibits, and Financial Statement Schedules

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)).

Exhibit No.	Description
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)).

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)).

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 Carlin, Charron & Rosen, LLP
24	Power of Attorney (included on the signature page hereto).
31.1	Certification by Chief Executive Officer Pursuant to Rule 13a 14.
31.2	Certification by Chief 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 Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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 12, 2008

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 12, 2008
/s/ Paul M. Feinstein Paul M. Feinstein	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2008
/s/ Harold S. Koplewicz Harold S. Koplewicz, M.D.	Chairman of the Board	March 12, 2008
/s/ Laura Philips Laura Philips, PhD	Director	March 12, 2008
/s/ Jonathan Lewis Jonathan Lewis, M.D.	Director	March 12, 2008
/s/ Robert Ladd Robert Ladd	Director	March 12, 2008