DELCATH SYSTEMS INC
Form 10-K
March 16, 2007

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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, 2006

[ ] 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.)
1100 Summer Street, Stamford, Connecticut (Address of principal executive offices)	06905 (Zip Code)

203-323-8668
(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	NASDAQ Small Cap Boston Stock Exchange

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

Common Stock, par value $0.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act.

Yes [ ] 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 [ ] 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 [ ]

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. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Act). Large accelerated filer [ ] Accelerated filer [X] Non-accelerated filer [ ]

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

Yes [ ] 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 $5.25 per share, was $98,834,096 as of June 30, 2006.

At March 1, 2007, the registrant had outstanding 21,252,613 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Incorporated into Part III of this Form 10-K.

Proxy Statement for 2007 Annual Meeting of Stockholders. (A 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 was incorporated under Delaware law in 1988. We are a 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. 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 phase III United States Food and Drug Administration (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. As mentioned, we are in the process of conducting a Phase III clinical trial designed to secure marketing approval in the United States and possibly in foreign markets 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 Phase II clinical trials. Additionally, we plan to conduct pre-clinical and clinical trials on the use of the Delcath System with other chemotherapy agents used to treat liver cancer. Since our inception, we have raised approximately $38.0 million in funds (net of fundraising expenses), and we have invested approximately $19.8 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 expand 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. Our strategy includes the following:

- 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 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 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. 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 device. 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. We intend to develop strategic alliances with a number of cancer centers. To this end, we are presently contacting recognized leading institutions and liver transplant centers that focus on regional cancer treatments. 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.

- We intend to improve 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 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 1,444,920 new cases of cancer would be diagnosed the United States in 2007. According to the American Cancer Society's "Cancer Facts and Figures 2007," 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. In the year 2006, the National Institutes of Health, in the American Cancer Society's "Cancer Facts & Figures 2007," estimated the overall costs of cancer to be $206.3 billion, including $78.2 billion in direct medical costs, $17.9 billion for indirect morbidity costs attributable to lost productivity due to illness and $110.2 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 2007," the five-year survival rate for liver cancer patients is approximately 10.5%, 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, 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 19,160 newly diagnosed cases of primary liver cancer in 2007 and the Company estimates that there will be approximately 222,000 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.

Surgery

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. Shrinking a tumor using chemotherapy and then removing the tumor surgically is a procedure known as adjuvant therapy. 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;
- It is associated with mortality rates estimated to be between one and five percent; and
- It is expensive compared to other alternatives.

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.

Implanted Infusion Pumps

Implanted infusion pumps can be used to better target the delivery of chemotherapy agents to the tumor. Arrow International markets an implantable pump typically used to treat colorectal cancer which has metastasized to the liver. 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 developed 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

Other liver cancer treatments include hepatic arterial infusion, embolization, chemo-embolization, radio frequency ablation, 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 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 while treating the diseased liver with high doses of chemotherapeutic agents and then returns 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 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 blood pump to push the isolated blood through the system's filters and guide the cleansed blood back to the patient.
- Filters -- two activated carbon hemoperfusion filters used to remove most of the chemotherapy agent from the isolated blood coming out of the liver before 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 some cases 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. 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. Under the SPA Agreement, a patient treated in the clinical trial as part of the non-Delcath control group who thereafter experiences tumor progression can, with his physician's approval, be crossed over and treated using the Delcath system. 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). Control patients whose tumors grow will have completed their portion of the trial and at the Principal Investigator's judgment will then be permitted to receive the Delcath treatment. Patients are currently being treated at NCI and additional sites are expected to be added to the trial during 2007.

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.

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, the Company announced that The National Institutes of Health/The National Cancer Institute 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 Phase I clinical trial conducted at The National Cancer Institute ("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 NCI.

The CRADA between Delcath and the NCI expired on December 14, 2006. It provides for a 30 day grace period by its terms, which has passed. We have been informed that the CRADA sub-committee of the NCI has approved an additional five-year Cooperative Research and Development Agreement with Delcath Systems. We are awaiting final signatures to formalize that agreement, and expect to renew this agreement with the NCI.

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 World Health Organization (WHO). 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 WHO figures. The Centers for Disease control 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.

Sales and Marketing

If we receive U. S. 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 recognized by NCI, 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 members of the hospital staff 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 initially four 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 believe that the Delcath system will provide significant cost savings in that it should reduce treatment and hospitalization costs associated with the side-effects of chemotherapy. Our planned wholesale price to the hospital for the Delcath system kit is approximately $4,000. A patient is expected to undergo an average of four treatments with the Delcath system, each requiring a new system kit, resulting in projected revenue of $16,000 per patient.

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 accessories and assembling the Delcath system kit. 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 and can, therefore, be sourced off the shelf. These components, however, 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 Investigational Device Exemption (IDE) approved by the FDA. Delcath is investigating the opportunity to collaborate 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, radio frequency ablation, radiation therapy, implanted infusion pumps, surgically isolated perfusion 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 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. It is subject to the most stringent controls applied by the FDA to assure reasonable safety and effectiveness. 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 sponsor 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 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 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 are in discussions with drug companies for this purpose, but 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.

If we successfully complete the Phase III clinical trial we believe a manufacturer of melphalan will submit to the FDA an application to deliver the agent to the liver through the Delcath system. 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 four corresponding foreign patents in Canada, Europe and Japan that we believe are or may be material to our business:

Summary Description of Patents	Patent No.
Isolated perfusion method for cancer treatment	U.S. #5,069,662
Isolated perfusion device -- catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479
Device and method for isolated pelvic perfusion	U.S. #5,817,046
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163
Isolated perfusion method for kidney cancer	U.S. #6,186,146
Catheter flow and lateral movement controller	U.S. #5,897,533
Method for treating glandular diseases and malignancies	U.S. #7,022,097

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 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, 2006 we had four 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

While Delcath maintains a website at www.delcath.com, it does not currently make available its Annual Reports on Form 10-K, its quarterly reports on Form 10-Q or its current reports on Form 8-K (or amendments thereto) available through its website. If Delcath determines that it will modify its website, it will consider making copies of such reports available through its website. Until such time as Delcath's periodic reports under the Securities Exchange Act of 1934 are available through its website, it will voluntarily provide copies of such reports free of charge upon request.

Copies of the periodic reports that we file under the Securities Exchange Act of 1934 and amendments to such reports are also available free of charge through a website maintained by the U.S. Securities and Exchange Commission at www.SEC.gov.

Item 1A. Risk Factors

You should consider carefully the following factors, as well as the other information set forth in this prospectus, prior to making an investment in our securities. If any of the following risks and uncertainties actually occur, 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

The following factors relate to risks that are material to our business and financial condition. If any of the possible events we describe below turns out to be the case, our business may be adversely affected and we may be forced to cease or curtail our operations which may result in the loss of your entire investment.

Our entire focus has been the development and commercialization of the Delcath system. If we are not successful in that development and commercialization, 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. 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, 2006, we have incurred cumulative losses of $35.3 million which were principally incurred in connection with our product development efforts and, in 2006, legal expenses. For the years ended December 31, 2005 and December 31, 2006, we incurred net losses of $2.9 million and $11.0 million, respectively.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003. Please see the detailed discussion of our various sales of securities described in Note 2 to our 2006 financial statements that are included herein. In addition, we received proceeds of approximately $5.6 million from private placements we completed in 2004, approximately $2.2 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; and approximately $5.1 million on exercise of warrants and options in 2006.

If we continue to incur losses we may exhaust our capital resources resulting in our being unable to complete the development and commercialization of our product. As we incur additional losses, our accumulated deficit will further increase. As of December 31, 2006, we had cash and cash equivalents and short term investments of $8.7 million.

We will likely need additional funding to complete the required clinical trials and our efforts to raise additional financing may be unsuccessful.

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 effectiveness of our system. We will likely need additional funding to complete the required clinical trials, and we may not be able to raise additional funds on reasonable terms or at all.

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 the Company where a patient's insurer agrees to cover treatment expenses. As a result, we are unable to estimate the total costs we will incur in completing the clinical trials. In

addition, completion of the clinical trials does not guarantee that the FDA will give us the required approvals in a timely manner or will give them to us at all.

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.

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. We have no commitments for any additional financing. If we are unable to obtain additional financing as needed, we will not be able to sell the system commercially.

Risks Related to FDA and Foreign Regulatory Approval

The following factors relate to risks that are material to obtaining FDA and foreign regulatory approval. If any of the events we describe below turns out to be the case, our business may be adversely affected and we may be forced to cease or curtail our operations which may result in the loss of your entire investment.

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. Separate FDA approval would be needed to market the system for use with other drugs or to treat other diseases. Lack of such specific approvals will limit our ability to market our product.

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. This 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 not able 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 arranging for clinical trials;
- in evaluating and submitting the data gathered from clinical trials;
- in designing trials to conform to the trial protocols authorized by the FDA;
- in complying with the requirements of institutional review boards at the sites where the trials may be conducted; and
- in 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 since 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 responding 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.

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.

Because the Delcath system currently is characterized by the FDA as an experimental device, Medicare, Medicaid and private health insurance plans will not reimburse its use in the United States. We will not begin to seek to have third-party payors reimburse 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. Third-party payors in the United States or abroad may decide not 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.

New products are under increased scrutiny as to whether or not they will be covered by the various healthcare plans and the level of reimbursement which will 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, 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 and assembles the Delcath system kit. 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 filtration pump head. The Company purchases 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.

We believe that our Chief Executive Officer and our Chief Operating Officer are important to our efforts to commercialize the Delcath system. The unavailability of the services of either of them could delay our successful commercial introduction of the Delcath system.

The loss of the services of either our Chief Executive Officer or our Chief Operating Officer could delay our completing the clinical trials, our obtaining FDA premarket approval, our introducing the Delcath system commercially and our generating revenues and profits. We do not have an employment agreement with either of them.

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.

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. 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. 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

The following factors relate to risks that are material to an investment in our common stock. Any of these factors could result in lowering the market value of our common stock and other securities that we might issue.

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, 2006, 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 March 31, 2004).

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.

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 the Company's 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 the Company's 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 shares of preferred stock in one or more series and to fix 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 were notified by the Nasdaq Capital Market on one occasion that we failed to meet the minimum bid price requirement and on two occasions that we did not meet the requirement that we meet one of the following conditions: that the market value of our common stock be at least $35 million; that we have stockholders' equity of not less than $2.5 million; or that we meet certain income tests. If we do not meet all of the 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.

Item 2. Properties.

We currently occupy approximately 3,600 square feet of office space at 1100 Summer Street, Stamford, Connecticut, on a month-to-month basis. We have occupied these facilities since 1992, 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 at commercially reasonable rates 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.

On August 4, 2006, the Company instituted a lawsuit against Robert Ladd, Laddcap Value Associates LLC and Laddcap Value Partners LP (collectively, the "Ladd Defendants") in the U.S. District Court for the District of Columbia. The lawsuit alleged that the Ladd Defendants had made a series of material misstatements and omissions in violation of the Securities Exchange Act of 1934 in its 13D filings, Valuation Proxy Solicitation and Schedule 14A Preliminary Proxy Statement for their proposed consent solicitation seeking to replace the Company's Board of Directors. The principal relief sought by the Company was an order: (a) enjoining the Ladd Defendants proposed consent solicitation until after a trial could be held on the merits; (b) mandating that the Ladd Defendants publicly correct their misstatements and omissions following a trial on the merits; and (c) prohibiting the Ladd Defendants from making any further misstatements and omissions.

On October 8, 2006, the Company entered into a Settlement Agreement resolving all issues outstanding with the Ladd Defendants. The agreement provided for the immediate appointment of Mr. Robert B. Ladd, 48, Principal of Laddcap Value Partners, to the Delcath Board of Directors and one additional independent director to be mutually agreed upon by Laddcap and the Company. The Company issued 100,000 shares of common stock to Laddcap as partial reimbursement for its expenses associated with the Consent Solicitation. As part of the agreement,

Laddcap is also permitted to increase its ownership in Delcath up to a maximum of 14.9% of Delcath's total outstanding common stock by purchasing additional shares of Delcath common stock directly and only from Delcath for a cash price equal to the 10 trading day average of the closing price of Delcath stock prior to the time that an additional purchase is made.

In conjunction with the resolution, Delcath agreed to terminate its lawsuit against the Ladd Defendants relating to its claims under Sections 13(d) and 14(a) of the Securities Exchange Act of 1934 and Laddcap agreed to end its attempt to remove the Delcath Board of Directors.

In addition, on August 4, 2006, the Company instituted a lawsuit against Jonathan Foltz by filing a complaint in the State of Connecticut Superior Court for the Judicial District of Stamford/Norwalk at Stamford. The complaint alleged that Mr. Foltz misappropriated and used various Delcath trade secrets and other proprietary information. The relief sought by the Company included a temporary and permanent injunction, money damages, including punitive damages, and attorney's fees.

On February 1, 2007, following the judge's ruling dismissing the injunction, the Company entered into a Settlement Agreement withdrawing the complaint and agreeing to pay a portion of Mr. Foltz's legal fees. On February 9, 2007, the Company announced it was retaining Mr. Foltz as an advisor.

We are 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 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. 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.

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

The information contained in the first three paragraphs of Item 3 hereof are incorporated herein by reference.

PART II

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

(a) Our common shares trade on the NASDAQ Capital Market and on the Boston Stock Exchange 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

	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

	2005	
	High	Low
Quarter ended March 31, 2005	$4.40	$2.25
Quarter ended June 30, 2005	4.10	1.92
Quarter ended September 30, 2005	3.38	2.60
Quarter ended December 31, 2005	3.90	2.78

Pursuant to the Settlement Agreement between the Company and the Ladd Defendants described in Item 3 above, the Company issued 100,000 shares of Common Stock to Laddcap Value Partners LP (having a value of $3.06 per share) as partial reimbursement for its expenses associated with the consent solicitation. The issuance of these shares was not registered under the Securities Act of 1933 in reliance on the exemption contained in Section 4(2) thereof and Rule 506 thereunder as an issuance solely to an accredited investor. The Company received no cash proceeds from the issuance of these shares. All other sales of equity securities by the Company during 2006 that were not registered under the Securities Act have been previously reported by the Company in a Quarterly Report on Form 10-QSB or a Current Report on Form 8-K.

As of March 8, 2007, there were approximately 80 stockholders of record of our Common Stock and approximately 3,975 additional beneficial owners of our Common Stock.

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, 2001 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.

Comparison of Five-Year Cumulative Total Return

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN
AMONG DELCATH SYSTEMS, INC.,
NASDAQ MARKET INDEX AND HEMSCOTT GROUP INDEX

[GRAPHIC OMITTED]

Company/Index/Market	2001	2002	2003	2004	2005	2006
Delcath Systems	100.00	147.32	81.25	268.75	303.57	330.36
Industry Group	100.00	25.69	37.22	54.41	49.00	45.33
NASDAQ Market Index	100.00	69.75	104.88	113.70	116.19	128.12

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.

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2006 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	Weighted average exercise price of outstanding options, and rights	Num rem for und com (ex ref (a)
	(a)	(b)	
Equity compensation plans approved by security holders	1,465,650	$2.87	
Equity compensation plans not approved by security holders	--	--	
Total	1,465,650	$2.87	

(b) Not applicable

(c) Not applicable

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, 2006, are derived from the financial statements of Delcath Systems, Inc. The financial statements as of December 31, 2006 and 2005 and for each of the three-year period ended December 31, 2006 (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."

	Years Ended December 31,				
	2006	2005	2004	2003	2002
	(Dollars in thousands)				
Statement of Operations Data					
Costs and expenses	$11,699	$3,112	$3,367	$2,306	$1,897
Operating loss	11,699	3,112	3,367	2,306	1,897
Net Loss	10,952	2,865	3,266	2,250	1,807

	Years Ended December 31,				
	2006	2005	2004	2003	2002
Balance Sheet Data					
Current assets	$8,760	$12,920	$7,338	$2,393	$1,536
Total assets	8,764	12,928	7,352	2,430	1,812
Current liabilities	670	330	565	260	175
Stockholder's equity	8,093	12,598	6,787	2,170	1,637

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 in the financial statements and the notes thereto. 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 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 drug delivery 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 Phase III protocol for the study of the Delcath drug delivery system for inoperable melanoma in the liver using melphalan under the Fast Track and SPA approved protocol.

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

We expect our available funds to be sufficient for our anticipated needs for working capital and capital expenditures through 2007 provided no studies using new agents or treating new organs are initiated outside of the CRADA with the NCI. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months.

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.

Future Capital Needs; Additional Future Funding

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance of its ever achieving consistent profitability. The Company believes its capital resources are adequate to fund operations for at least the next twelve months but anticipates that it will require additional working capital after 2007. There can be no assurance that such working capital will be available on acceptable terms, if at all.

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, 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" 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 Securities and Exchange Commission (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 Form 10-Q, Form 8-K and Form 10-K reports filed with the Commission.

Application of Critical Accounting Policies

The Company's 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 Delcath's financial statements. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under accounting principles generally accepted in the United States of America.

Additionally, the Company devotes 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 the Company's choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying 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 the Company will realize the benefits of its 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. The Company adopted SFAS 123(R) in 2005.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

The Company does not use derivative financial instruments. 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.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm
Balance Sheets as of December 31, 2006 and 2005
Statements of Operations for the years ended December 31, 2006, 2005, and 2004 and cumulative from inception (August 5, 1988) to December 31, 2006 Statements of Stockholders' Equity for the years ended December 31, 2006, 2005, and 2004 and cumulative from inception (August 5,
1988) to December 31, 2006
Statements of Cash Flows for the years ended December 31, 2006, 2005, and 2004 and cumulative from inception (August 5, 1988) to December 31, 2006 Notes to Financial Statements

Selected Quarterly Financial Data

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2006 and 2005.

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

	2005 Quarters Ended (in thousands except per share amounts)			
	March 31	June 30	September 30	December 31
Net sales	$ 0	$ 0	$ 0	$ 0
Gross Profit	0	0	0	0
Net loss	915	625	645	680
Loss per share	0.06	0.04	0.04	0.04

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

In connection with the audits for each of the years in the two-year period ended December 31, 2004 and for the period from August 5, 1988 (inception) to December 31, 2004, and the subsequent interim period through April 25, 2005, except for a reportable condition with respect to the Company's internal controls regarding identifying the Company's awards of stock options which awards were described in the Company's Form 8-K reports dated March 22, 2005 and April 5, 2005, there were no disagreements between the Company and Eisner LLP, the Company's former accountant, on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to Eisner LLP's satisfaction, would have caused Eisner LLP to make reference to the subject matter of the disagreement (s) in connection with its reports.

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, 2006. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2006, our disclosure controls and procedures were (1) effective in accumulating and communicating information to the Company's management, as appropriate, to allow timely decisions regarding required disclosure (2) effective, in that that they provide reasonable assurance that information

required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control over Financial Reporting

The management of Delcath Systems, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control of financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 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.

Delcath System, Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2006. 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 our assessment, we concluded that, as of December 31, 2006, the Company's internal control over financial reporting is effective based on those criteria.

Carlin, Charron & Rosen, LLP, Delcath System, Inc.'s Independent Registered Public Accounting Firm, audited our assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2006, as stated in their report appearing under Item 8.

Changes in Internal Control over Financial Reporting

No change in the Company's internal control over financial reporting occurred during the fiscal year ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

There was no information that we were required to disclose in a Current Report on Form 8-K during the fourth quarter of the year ended December 31, 2006 that

we have not previously 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 is incorporated by reference into this Form 10-K by reference to the Company's definitive proxy statement (the "Definitive Proxy Statement") for its 2007 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 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 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, if any, is incorporated into this Form 10-K by reference to the Definitive Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by Item 9(e) of Schedule 14A 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 Registrant's Current Report on Form 8-K dated 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 Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

4.1 Rights Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.7 to Registrant's Form 8-A dated November 12, 2001 (Commission File No. 001-16133)).

4.2 Form of Underwriter's Unit Warrant Agreement between Delcath Systems, Inc. and Roan/Meyers Associates L.P. (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant'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

Exhibit No. Description

(incorporated by reference to Exhibit 4 to Registrant's Current Report on Form 8-K dated March 19, 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 Registrant's Current Report on Form 8-K dated November 28, 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 Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 011-16133)).

10.1 2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant'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 Registrant'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 Registrant'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 Registrant's Current Report on Form 8-K dated March 19, 2004 (Commission File No. 001-16133)).

10.5 Registration Rights Agr eement 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 Registrant's Current Report on Form 8-K dated March 19, 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 Schedule I thereto (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).

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 Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).

10.8 Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005)).

10.9 Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005)).

10.10 Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).

10.11 Settlement Agreement, dated as of October 8, 2006, by and between Delcath Systems, Inc., Laddcap Value Partners LP, Laddcap Value

Exhibit No. Description

Advisors LLC, Laddcap Value Associates LLC, any affiliate of the foregoing, and Robert B. Ladd (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated October 8, 2006 (Commission File No. 001-16133)).

10.12 Settlement Agreement, dated as of December 15, 2006 between Delcath Systems, Inc. and M. S. Koly (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated December 21, 2006 (Commission File No. 001-16133)).

14 Code of Business Conduct (incorporated by reference to Exhibit 14 to Registrant'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.
Registrant

/s/ RICHARD TANEY

Richard Taney, Chief Executive Officer
March 16, 2007

Each person whose signature appears below appoints Richard L. Taney as his attorney-in-fact, with full power of substitution and resubstitution 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

/s/ RICHARD TANEY Richard Taney	Chief Executive Officer, and Director (Principal Executive Officer)	
/s/ PAUL M. FEINSTEIN Paul M. Feinstein	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	
/s/ HAROLD S. KOPLEWICZ Harold S. Koplewicz, M.D.	Chairman of the Board	M
/s/ MARK A. CORIGLIANO Mark A. Corigliano	Director	M
/s/ DANIEL L. ISDANER Daniel L. Isdaner	Director	M
/s/ SAMUEL HERSCHKOWITZ Samuel Herschkowitz, M.D.	Director	M
/s/ ROBERT LADD Robert Ladd	Director	M

DELCATH SYSTEMS, INC.
DRAFT 3/12/07
(A Development Stage Company)

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Index to Financial Statements

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. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2006 and cumulative from incepion (August 5, 1988) to December 31, 2006. We also have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that Delcath Systems, Inc. maintained effective internal control over financial reporting as of December 31, 2006 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. Our responsibility is to express an opinion on these financial statements, an opinion on management's assessment, and an opinion on the effectiveness of 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 audit of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and 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, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006 and cumulative from inception (August 5, 1988) to December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, management's assessment that Delcath Systems Inc. maintained effective internal control over financial reporting as of December 31, 2006 is fairly stated, in all material respects, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Furthermore, in our opinion, Delcath Systems, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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 15, 2007

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Balance Sheets

	December 31, 2006	Decem 2
Assets		
Current assets		
Cash and cash equivalents	$ 6,289,723	$
Certificates of deposit	2,408,302	1
Interest receivable	-	
Prepaid insurance	61,917	

Total current assets	8,759,942	1
Property and equipment, net	3,719	
Total assets	$ 8,763,661	$ 1
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 670,367	$
Total current liabilities	670,367	
Commitments and contingencies (Note 5)	--	
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	--	
Common stock, $.01 par value; 70,000,000 shares authorized; 20,688,863 shares issued and 20,660,763 outstanding (2006) 18.877,753 shares issued and 18,849,653 outstanding (2005)	206,608	
Additional paid-in capital	44,673,458	3
Deficit accumulated during development stage	(36,786,772)	(2
Total stockholders' equity	8,093,294	1
Total liabilities and stockholders' equity	$ 8,763,661	$ 1

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Operations

	Year ended December 31,		
	2006	2005	2004
Costs and expenses			

General and administrative expenses	$ 8,980,424	$ 1,367,344	$ 1,059,815
Research and development costs	2,718,084	1,744,251	2,306,733
Total costs and expenses	11,698,508	3,111,595	3,366,548
Operating loss	(11,698,508)	(3,111,595)	(3,366,548)
Other income (expense)			
Interest income	620,403	246,976	100,216
Other Income	126,500	--	--
Interest expense	--	--	--
Net loss	$ (10,951,605)	$ (2,864,619)	$ (3,266,332)
Common share data			
Basic and diluted loss per share	$ (0.55)	$ (0.18)	$ (0.28)
Weighted average number of basic and diluted common shares outstanding	19,906,932	16,038,716	11,543,256

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Statements of Stockholders' Equity

Years ended December 31, 2006, 2005 and 2004
cumulaive from inception (August 5, 1988) to December 31, 2006

	Common stock $.01 par value				
	Issued		In treasury		Out
	No. of shares	Amount	No. of shares	Amount	No sh
Shares issued in connection with the					

formation of the Company as of August 22, 1988	621,089	$ 6,211	--	$ --	62
Sale of preferred stock, August 22, 1988	--	--	--	--	
Shares returned due to relevant technology milestones not being fully achieved, March 8, 1990	--	--	(414,059)	(4,141)	(41
Sale of stock, October 2, 1990	--	--	17,252	173	1
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	4
Sale of stock, August 30, 1991	--	--	1,353	14	
Sale of stock, December 31, 1992	--	--	103,515	1,035	10
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	10
Sale of stock, December 19, 1996					
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	--	--	39,512	395	3
Sale of stock, December 31, 1997	58,491	585	98,388	984	15
Exercise of stock options	53,483	535	--	--	5
Shares issued as compensation for consulting services valued at $10.87 per share based on a 1996 agreement	13,802	138	3,450	35	1
Shares issued in connection with exercise of warrants	2,345	23	828	8	
Sale of stock, January 16, 1998	21,568	216	--	--	2
Sale of stock, September 24, 1998	34,505	345	--	--	3
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)	--	--	(
Exercise of stock options	8,626	86	--	--	
Sale of stock (including 5,218 warrants each to purchase one share of common stock at $14.87), June 30, 1999	46,987	470	--	--	4

	Preferred Stock		Class A preferred stock	
	$.01 par value		$.01 par value	
	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988	--	$ --	--	$ --
Sale of preferred stock, August 22, 1988	--	--	2,000,000	20,000
Shares returned due to relevant technology milestones not being fully achieved,				

March 8, 1990	--	--	--	--
Sale of stock, October 2, 1990	--	--	--	--
Sale of stock (common stock at $7.39 per share and Class B preferred stock at $2.55 per share), January 23, 1991	--	--	--	--
Sale of stock, August 30, 1991 Sale of stock, December 31, 1992 Sale of stock (including 10,318 warrants, each to purchase one share of common stock at $10.87), July 15, 1994	--	--	--	--
Sale of stock, December 19, 1996	--	--	--	--
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	--	--	--	--
Sale of stock, December 31, 1997	--	--	--	--
Exercise of stock options	--	--	--	--
Shares issued as compensation for consulting services valued at $10.87 per share based on a 1996 agreement	--	--	--	--
Shares issued in connection with exercise of warrants	--	--	--	--
Sale of stock, January 16, 1998	--	--	--	--
Sale of stock, September 24, 1998	--	--	--	--
Shares returned as a settlement of a dispute with a former director at $1.45 per share, the price originally paid, April 17, 1998	--	--	--	--
Exercise of stock options	--	--	--	--
Sale of stock (including 5,218 warrants each to purchase one share of stock at $14.87), June 30, 1999	--	--	--	--

	Additional paid-in capital	Deficit accumulated during development stage	Total
Shares issued in connection with the formation of the Company as of August 22, 1988	$ (5,211)	$ --	$ 1,000
Sale of preferred stock, August 22, 1988	480,000	--	500,000
Shares returned due to relevant technology milestones not being fully achieved, March 8, 1990	4,141	--	--
Sale of stock, October 2, 1990	24,827	--	25,000
Sale of stock (common stock at $7.39 per share and Class B preferred stock at $2.55			

per share), January 23, 1991	1,401,690	--	1,406,322
Sale of stock, August 30, 1991 Sale of stock,	9,987	--	10,001
December 31, 1992 Sale of stock (including 10,318 warrants,	1,013,969	--	1,015,004
each to purchase one share of common stock at $10.87), July 15, 1994	1,120,968	--	1,122,000
Sale of stock, December 19, 1996	999,605	--	1,000,000
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	1,703,395	--	1,704,964
Sale of stock, December 31, 1997	774,465	--	775,000
Exercise of stock options	30,827	--	31,000
Shares issued as compensation for consulting services valued at $10.87 per share based on a 1996 agreement	34,454	--	34,485
Shares issued in connection with exercise of warrants	234,182	--	234,398
Sale of stock, January 16, 1998	499,655	--	500,000
Sale of stock, September 24, 1998	56,965	--	57,000
Shares returned as a settlement of a dispute with a former director at $1.45 per share, the price originally paid, April 17, 1998	(4,965)	--	(5,000)
Exercise of stock options	67,414	--	67,500
Sale of stock (including 5,218 warrants each to purchase one share of common stock at $14.87), June 30, 1999	775,722	--	776,192

	Common stock $.01 par value				
	Issued		In treasury		Out
	No. of shares	Amount	No. of shares	Amount	No sh
Shares issued in connection with exercise of warrants	2,300	23	--	--	
Sale of stock, April 14, 2000	230,873	2,309	--	--	23
Dividends paid on preferred stock	690,910	6,909	--	--	69
Conversion of preferred stock	833,873	8,339	--	--	83
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	--	--	1,20
Shares issued as compensation for stock sale	85,000	850	--	--	8
1,720 stock options (including 1,720 warrants each to purchase one share of common stock at $6.00), issued as compensation	--	--	--	--	
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	--	--	
Stock warrants (150,000 at $7.00 and 150,000 at $6.60) issued as compensation	--	--	--	--	

Sale of stock on April 3, 2002	243,181	2,432	--	--	24
Repurchases of stock, November and December 2002			(28,100)	(281)	(2
Amortization since inception of compensatory stock options	--	--	--	--	
Forfeiture since inception of stock options	--	--	--	--	
Sale of stock (including 3,895,155 warrants to purchase one share of common stock at $0.775) on May 20, 2003 including under-writer's exercise of overallotment option	3,895,155	38,952	--	--	3,89
Proceeds from sale of unit option	--	--	--	--	
Exercise of 2003 Warrants	1,730,580	17,305	--	--	1,73
Sale of stock, March, 2004	1,197,032	11,970	--	--	1,19
Exercise of 2002 Warrants	20,265	203	--	--	2
Sale of stock, April, 2004	290,457	2,905	--	--	29
Stock options issued as compensation	--	--	--	--	
Sale of stock, November, 2004	1,069,520	10,695	--	--	1,06
Sale of stock, December, 2004	236,966	2,370	--	--	23
Exercise of 2003 Warrants	2,160,163	21,602	--	--	2,16
Exercise of 2003 Representative's Unit Warrants	282,025	2,820	--	--	28
Exercise of Representative's Common Stock Warrants	152,025	1,520	--	--	15
Exercise of stock options	62,000	620	--	--	6
Deficit accumulated from inception to December 31, 2004	--	--	--	--	
Balance at December 31, 2004	15,243,185	$152,432	(28,100)	$(281)	15,21

	Preferred Stock		Class A preferred stock	
	$.01 par value		$.01 par value	
	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with exercise of warrants	--	--	--	--
Sale of stock, April 14, 2000	--	--	--	--
Dividends paid on preferred stock	--	--	--	--
Conversion of preferred stock	--	--	(2,000,000)	(20,000)
Sale of stock (including 1,200,000 warrants each to purchase one shar stock at $6.60), October 19, 2000	--	--	--	--
Shares issued as compensation for stock sale	--	--	--	--
1,720 stock options (including 1,720 warrants each to purchase one share of common stock at $6.00), issued as compensation	--	--	--	--
Sum of fractional common shares cancelled after year 2000 stock splits	--	--	--	--
Stock warrants (150,000 at $7.00 and 150,000				

at $6.60) issued as compensation	--	--	--	--
Sale of stock on April 3, 2002	--	--	--	--
Repurchases of stock, November and December 2002	--	--	--	--
Amortization since inception of compensatory stock options	--	--	--	--
Forfeiture since inception of stock options	--	--	--	--
Sale of stock (including 3,895,155 warrants to purchase one share of common stock at $0.775) on May 20, 2003 including under-writer's exercise of overallotment option	--	--	--	--
Proceeds from sale of unit option	--	--	--	--
Exercise of 2003 Warrants	--	--	--	--
Sale of stock, March, 2004	--	--	--	--
Exercise of 2002 Warrants	--	--	--	--
Sale of stock, April, 2004	--	--	--	--
Stock options issued as compensation	--	--	--	--
Sale of stock, November, 2004	--	--	--	--
Sale of stock, December, 2004	--	--	--	--
Exercise of 2003 Warrants	--	--	--	--
Exercise of 2003 Representative's Unit Warrants	--	--	--	--
Exercise of Representative's Common Stock Warrants	--	--	--	--
Exercise of stock options	--	--	--	--
Deficit accumulated from inception to December 31, 2004	--	--	--	--
Balance at December 31, 2004	--	$ --	--	$ --

	Additional paid-in capital	Deficit accumulated during development stage	Total
Shares issued in connection with exercise of warrants	24,975	--	24,998
Sale of stock, April 14, 2000	499,516	--	501,825
Dividends paid on preferred stock	992,161	(1,498,605)	(499,535)
Conversion of preferred stock	15,828	--	--
Sale of stock (including 1,200,000 warrants each to purchase one share of common stock at $6.60), October 19, 2000	5,359,468	--	5,371,468
Shares issued as compensation for stock sale	(850)	--	--
1,720 stock options (including 1,720 warrants each to purchase one share of common stock at $6.00), issued as compensation	3,800	--	3,800
Sum of fractional common shares cancelled after year 2000 stock splits	1	--	--
Stock warrants (150,000 at $7.00 and 150,000 at $6.60) issued as compensation	198,000	--	198,000

Sale of stock on April 3, 2002	265,068	--	267,500
Repurchases of stock, November and December 2002	(50,822)	--	(51,103)
Amortization since inception of compensatory stock options	3,760,951	--	3,760,951
Forfeiture since inception of stock options	(1,240,780)	--	(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 under-writer's exercise of overallotment option	1,453,696	--	1,492,648
Proceeds from sale of unit option	68	--	68
Exercise of 2003 Warrants	1,273,895	--	1,291,200
Sale of stock, March, 2004	2,660,625	--	2,672,595
Exercise of 2002 Warrants	26,547	--	26,750
Sale of stock, April, 2004	635,130	--	638,035
Stock options issued as compensation	5,222	--	5,222
Sale of stock, November, 2004	1,829,305	--	1,840,000
Sale of stock, December, 2004	497,630	--	500,000
Exercise of 2003 Warrants	1,652,524	--	1,674,126
Exercise of 2003 Representative's Unit Warrants	284,383	--	287,203
Exercise of Representative's Common Stock Warrants	193,072	--	194,592
Exercise of stock options	44,040	--	44,660
Deficit accumulated from inception to December 31, 2004	--	(21,471,943)	(21,471,943)
Balance at December 31, 2004	$ 29,605,543	$(22,970,543)	$ 6,787,146

	Common stock $.01 par value				
	Issued		In treasury		Ou
	No. of shares	Amount	No. of shares	Amount	No sh
Exercise of 2003 Representative's Unit Warrants	42,180	422	--	--	42
Exercise of Representative's Common Stock Warrants	157,180	1,572	--	--	157
Exercise of stock options	597,000	5,970	--	--	597
Stock options issued as compensation	--	--	--	--	
Exercise of 2004 Warrants	1,107,313	11,073	--	--	1,107
Exercise of 2005 Warrants	940,957	9,410	--	--	940
Sale of stock, November, 2005	753,013	7,530	--	--	753
Shares issued as compensation	36,925	369	--	--	36
Net Loss	--	--	--	--	
Balance at December 31, 2005	18,877,753	$188,778	(28,100)	$(281)	18,849
Vesting of stock options	--	--	--	--	--
Stock options issued as compensation	--	--	--	--	--
Exercise of 2003 Representative's Unit Warrants	6,250	62	--	--	6,2

Exercise of Representative's Common Stock Warrants	6,250	63	--	--	6,2
Exercise of 2004 Warrants	1,165,210	11,652	--	--	1,165,2
Exercise of 2005 Warrants	429,218	4,292	--	--	429,2
Exercise of stock options	104,182	1,042	--	--	104,1
Shares issued in connection with settlement of Consent Solicitation lawsuit	100,000	1,000	--	--	100,0
Net Loss	--	--	--	--	-
Balance at December 31, 2006	20,688,863	$ 206,889	(28,100)	$(281)	20,66

	Preferred Stock $.01 par value		Class A preferred stock $.01 par value	
	No. of shares	Amount	No. of shares	Amount
Exercise of 2003 Representative's Unit Warrants	--	--	--	--
Exercise of Representative's Common Stock Warrants	--	--	--	--
Exercise of stock options	--	--	--	--
Stock options issued as compensation	--	--	--	--
Exercise of 2004 Warrants	--	--	--	--
Exercise of 2005 Warrants	--	--	--	--
Sale of stock, November, 2005	--	--	--	--
Shares issued as compensation	--	--	--	--
Net Loss	--	--	--	--
Balance at December 31, 2005	----	------	----------	----------
Vesting of stock options	--	$ --	--	$ --
Stock options issued as compensation	--	--	--	--
Exercise of 2003 Representative's Unit Warrants	--	--	--	--
Exercise of Representative's Common Stock Warrants	--	--	--	--
Exercise of 2004 Warrants	--	--	--	--
Exercise of 2005 Warrants	--	--	--	--
Exercise of stock options	--	--	--	--
Shares issued in connection with settlement of Consent Solicitation lawsuit	--	--	--	--
Net Loss	--	--	--	--
	--	--	--	--
Balance at December 31, 2006	----	------	----------	----------

	Additional paid-in capital	Deficit accumulated during development stage	Total
Exercise of 2003 Representative's Unit Warrants	42,686	--	43,108
Exercise of Representative's Common Stock Warrants	200,619	--	202,191
Exercise of stock options	525,140	--	531,110
Stock options issued as compensation	8,270	--	8,270
Exercise of 2004 Warrants	2,883,418	--	2,894,491
Exercise of 2005 Warrants	2,573,363	--	2,582,773
Sale of stock, November, 2005	2,302,471	--	2,310,001
Shares issued as compensation	103,056	--	103,425
Net Loss	--	(2,864,619)	(2,864,619)
Balance at December 31, 2005	$ 38,244,566	$(25,835,167)	$12,597,89
Vesting of stock options	446,000	--	446,000
Stock options issued as compensation	505,282	--	505,282
Exercise of 2003 Representative's Unit Warrants	7,131	--	7,193
Exercise of Representative's Common Stock Warrants	7,132	--	7,195
Exercise of 2004 Warrants	3,306,090	--	3,317,742
Exercise of 2005 Warrants	1,557,233	--	1,561,525
Exercise of stock options	295,024	--	296,066
Shares issued in connection with settlement of Consent Solicitation lawsuit	305,000	--	306,000
Net Loss		(10,951,605)	(10,951,605)
Balance at December 31, 2006	$ 44,673,458	$ (36,786,772)	$ 8,093,294

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31, 2006	2005	2004

Cash flows from operating activities:			
Net loss	$ (10,951,605)	$ (2,864,619)	$ (3,266,332
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	1,042,448	8,270	5,222
Stock and warrant compensation expense issued for legal settlement and consulting services	306,000	103,425	--
Depreciation expense	3,835	6,052	5,526
Amortization of organization costs	--	--	--
Rent expense attributable to lease deposit	--	--	24,000
Changes in assets and liabilities:			
(Increase) decrease in prepaid expenses	(35,000)	20,899	(316
Decrease (increase) in interest receivable	91,574	(58,688)	(18,614
Increase (decrease) in accounts payable and accrued expenses	340,297	(234,556)	304,426
Net cash used in operating activities	(9,202,451)	(3,019,217)	2,946,088
Cash flows from investing activities:			
Purchase of furniture and fixtures	--	--	(5,345
Purchase of short-term investments	(5,424,548)	(11,097,790)	(6,052,383
Proceeds from maturities of short-term investments	14,114,036	7,055,129	1,014,575
Organization costs	--	--	--
Net cash used in investing activities	8,689,488	(4,042,661)	(5,043,153
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	5,098,555	8,563,674	7,877,961
Repurchases of common stock	--	--	--
Dividends paid	--	--	--
Proceeds from short-term borrowings	--	--	--
Net cash provided by financing activities	5,098,555	8,563,674	7,877,961
Increase (decrease) in cash and cash equivalents	4,585,592	1,501,796	(111,280
Cash and cash equivalents at beginning of period	1,704,131	202,335	313,615
Cash and cash equivalents at end of period	$ 6,289,723	$ 1,704,131	$ 202,335
Supplemental cash flow information:			
Cash paid for interest	$ --	$ --	$ --
Supplemental non-cash activities:			
Cashless exercise of stock options	$ 91,166	$ --	$ --
Conversion of debt to common stock	$ --	$ --	$ --
Common stock issued for preferred stock dividends	$ --	$ --	$ --

Conversion of preferred stock to common stock	$ --	$ --	$ --
Common stock issued as compensation for stock sale	$ --	$ --	$ --

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Financial Statements

December 31, 2006, 2005 and 2004

(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 IDE (Investigational Device Exemption) and an IND status (Investigational New Drug) for its product by the FDA (Food and Drug Administration). 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 $41,481 at December 31, 2006 and $37,646 at December 31, 2005. Depreciation expense for the years ended December 31, 2006, 2005 and 2004 was $3,835, $6,052 and $5,526, respectively. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

(d) Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with 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 on 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.

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. Unvested options having exercise prices of $2.78 and $3.59 per share, representing the right to purchase a total of approximately 1 million shares, became exercisable as a result of the vesting acceleration. All other terms and conditions in the original grants remain unchanged. 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.

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 years ended December 31, 2005 and 2004 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 years ended December 31, 2005 and 2004 are presented below.

	2005	2004
Net loss	$ (2,864,619)	$ (3,266,332)
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0
Stock-based employee compensation expense determined under the fair value based method, net of related tax effects	(133,194)	(93,793)
Pro forma net loss	$ (2,997,813)	$ (3,360,125)
Loss per share (basic and diluted):		
As reported	$ (0.18)	$ (0.28)
Pro forma	(0.19)	(0.29)

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. There were no stock option grants in 2004.

The per share weighted average fair value of five-year stock options granted in Novermber 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, 2006, 2005 and 2004 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 15% of the Company's then outstanding common stock have been excluded from the EPS computation.

(g) Recent Accounting Pronouncements

In September, 2006, the FASB issued SFAS No. 157 "Fair Value Measurements," which provides a definition of fair value, establishes a framework for measuring fair value and requires expanded disclosures about fair value measurements. The measurement and disclosure requirements, which are applied prospectively, are effective for the Company beginning in the first quarter of 2008. Management is assessing the potential impact on the Company's financial condition and results of operations.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" (SFAS No. 109). The interpretation contains a two step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 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 provisions are effective for the Company beginning in the first quarter of fiscal 2007. The Company does not anticipate that adoption of this statement will have any material impact on its financial statements.

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(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.

(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) Reclassification

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.

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.

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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 of 1933.

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 of 1933.

During 2004, the Company received net proceeds of $1,674,126 as 2,160,163 of the 2003 Warrants 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 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.

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 Securites Act of 1933.

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 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.

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 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.

(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 has 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 Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the terms and conditions of each award, the option price and the duration of each award.

During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and the 2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for 2006, 2005, and 2004 is as follows:

	The Plans			
	Stock Options	Exercise Price Per Share	Weighted Average Exercise Price	Weig Aver Remain (Ye
Outstanding at December 31, 2003	1,520,684	$0.60 - $4.93	$2.09	2.9
Exercised	(62,000)	$0.71 - $1.03	.72	
Expired	(441,664)	$2.90 - $4.93	4.14	

	The Plans			
	Stock Options	Exercise Price Per Share	Weighted Average Exercise Price	Weig Aver Remain (Ye
Outstanding at December 31, 2004	1,017,020	$0.60 - $3.31	$1.28	2

Granted	967,500	$2.78 - $3.59	3.20	
Expired	(1,720)	$3.31	3.31	
Exercised	(597,000)	$0.60 - $1.03	.89	
Outstanding at December 31, 2005	1,385,800	$0.71 - $3.59	$2.51	4
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	$.71 - $3.59	$2.87	3.

At December 31, 2006, 2005 and 2004, options for 1,465,650, 394,300, and 737,520 shares, respectively, were exercisable at a weighted average exercise price of $2.87, $1.89 and $1.30 per share, respectively. The aggregate intrinsic value of options outstanding and exercisable at December 31, 2006 is $1,218,453. 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 $3.70 as of December 31, 2006, which would have been received by the option holders had those option holders exercised their options as of that date.

(d) Warrants

A summary of warrant activity is as follows:

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weig Aver Remain (Y
Outstanding at December 31, 2003	4,628,970	$0.775 - 10.50	$3.17	3.35
Issued	2,537,668	$2.60 - 3.01	2.76	
Exercised	(2,614,478)	$0.775 -1.32	0.84	
Expired	(19,412)	$0.775 - 1.28	1.17	
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	

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	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weig Aver Remain (Yea
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	3.2
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	3.0

(3) Income Taxes

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

	Year Ended 2006	Year Ended 2005	Year Ended 2004
Income taxes using U.S. federal statutory rate	$(3,723,546)	(973,970)	(1,110,553)
State income taxes, net of federal benefit	(789,599)	(143,644)	(107,452)
Valuation allowance	4,483,576	1,072,032	1,151,549
Expiration of net operating losses	96,959	58,257	64,919
Other	(67,390)	(12,675)	1,537
	$ 0	0	0

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

	2006	2005
Deferred tax assets:		
Employee compensation accruals.....	$379,543	$0
Accrual to cash	243,015	82,410
Net operating losses.....	7,923,698	3,980,270
Total deferred tax assets.....	8,546,256	4,062,680
Valuation allowance	8,546,256	4,062,680
Net deferred tax assets.....	$0	$0

As of December 31, 2006 and December 31, 2005, the Company had net operating loss carryforwards for federal income tax purposes of approximately $30,223,000 and $20,705,000, 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 $16,974,000 is available to offset future federal taxable income which expires through 2026. As of December 31, 2006 and December 31, 2005, the Company had net operating loss carryforwards for state income tax purposes of approximately $22,450,000 and $12,647,000, respectively, which expire through 2026.

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 $4.5 million, $1.1 million and $1.1 million in 2006, 2005 and 2004, respectively.

(4) Rents

The Company currently occupies its office space on a month-to-month basis. Rent expense totaled $87,376 for each of the years ended December 31, 2006, 2005 and 2004.

(5) Contingencies

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

(5) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2006 and 2005.

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

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2005 Quarters Ended (in thousands except per share amounts)	March 31	June 30	September 30	December 31
Net sales	$ 0	$ 0	$ 0	$ 0
Gross Profit	0	0	0	0
Net loss	915	625	645	680
Loss per share	0.06	0.04	0.04	0.04

EXHIBIT INDEX

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 Registrant's Current Report on Form 8-K dated 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 Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.1	Rights Agreement, dated October 30, 2001, by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.7 to Registrant's Form 8-A dated November 12, 2001 (Commission File No. 001-16133)).

4.2 Form of Underwriter's Unit Warrant Agreement between Delcath Systems, Inc. and Roan/Meyers Associates L.P. (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to Registrant'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 Registrant's Current Report on Form 8-K dated March 19, 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 Registrant's Current Report on Form 8-K dated November 28, 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 Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 011-16133)).

10.1 2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant'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 Registrant'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 Registrant'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 Registrant's Current Report on Form 8-K dated March 19, 2004 (Commission File No. 001-16133)).

10.5 Registration Rights Agr eement 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 Registrant's Current Report on Form 8-K dated March 19, 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 Schedule I thereto (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).

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 Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).

10.8 Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005)).

10.9 Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005)).

10.10 Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).

10.11 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 Registrant's Current Report on Form 8-K dated October 8, 2006 (Commission File No. 001-16133)).

10.12 Settlement Agreement, dated as of December 15, 2006 between Delcath Systems, Inc. and M. S. Koly (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated December 21, 2006 (Commission File No. 001-16133)).

14 Code of Business Conduct (incorporated by reference to Exhibit 14 to Registrant'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).