UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-KSB

[X] Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2005

[_} Transition report under 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.
(Name of Small Business Issuer in its charter)

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
(Issuer's telephone number)

Securities registered under Section 12(b) of the Exchange 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 under to Section 12(g) of the Exchange Act:

Common Stock, par value $0.01 per share

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. [_]

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 [_]

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. [_]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [_] No [X]

The issuer's revenues for its most recent fiscal year were: $0.

The aggregate market value of the voting common stock held by non-affiliates of the issuer, based on the closing sales price of $4.50 per share, was $86,807,997 as of February 28, 2006.

At March 16, 2006, the registrant had outstanding 19,290,666 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Incorporated into Part III of this Form 10-KSB.

Proxy Statement for 2006 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-KSB).

Transitional Small Business Disclosure Format (check one):

Yes [_] No [X]

PART I

Item 1. Description of Business.

General

We were incorporated under Delaware law in 1988. We are a development stage company, and we have developed the Delcath system to isolate the liver from the general circulatory system in order to administer chemotherapy and other therapeutic agents directly to the liver. Since our inception, we have raised approximately $32.9 million in funds (net of fundraising expenses), and we have invested approximately $17.1 million of those funds in research and development costs associated with development and testing of the Delcath system.

The Delcath system is not currently approved for marketing by the United States Food and Drug Administration (FDA), and it cannot be marketed in the United States without FDA pre-market approval. We are in the process of conducting two Phase III clinical trials designed to secure marketing approval in the United States and possibly in foreign markets for use of the Delcath system with the chemotherapy agents, melphalan and doxorubicin, currently being tested in the treatment of malignant melanoma that has spread to the liver. We also plan to continue our Phase II clinical trial for the use of the Delcath system with one of these chemotherapy agents, melphalan, against primary liver cancer and a variety of cancers that have spread to the liver. 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.

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 or doxorubicin to treat malignant melanoma that has spread to the liver. Our highest priority is completing Phase III clinical trials with either or both of these agents, data preparation, statistical analysis and regulatory documents associated with an application for pre-market approval of commercial sale of the Delcath system in the United States for use in administering melphalan or doxorubicin in the treatment of melanoma that has spread to the liver.

- Obtaining approval to market the Delcath system in the United States for the treatment of additional cancers in the liver, such as primary liver cancers and colorectal cancers that have spread to the liver using melphalan, doxorubicin and other chemotherapy agents and treatment of hepatitis using anti-viral drugs. In 2004, we commenced Phase II studies of three cancers in the liver other than melanoma and are currently recruiting and treating patients within this protocol. In addition to researching the use of other chemotherapy agents with the Delcath system to treat cancer, we plan to research the use of other compounds with the Delcath system to treat other diseases, such as hepatitis. Our timing to begin these studies may depend on our ability to raise additional funds for these purposes and will likely depend on our ability to establish strategic alliances with pharmaceutical manufacturers or other strategic partners in conjunction with our research into other therapeutic compounds. Additional FDA pre-market approvals will be required to market the Delcath system for these uses.

- Introducing the Delcath system into foreign markets. We will seek to establish strategic relationships with domestic and foreign firms that have a recognized presence or experience in foreign markets that we intend to target. Our strategy is to focus on markets that have a high incidence of liver cancer and the means to provide and pay for cancer treatments. According to the World Health Organization, many Asian and European countries, including China, Japan, Greece, Hong Kong, the Philippines, Australia, France, Germany, Italy and Spain, have a higher incidence of liver cancer than the United States. We intend to seek to enter into

arrangements with strategic partners who have experience with obtaining regulatory approval and marketing medical devices in those markets and are willing to bear the cost of those activities.

The Cancer Treatment Market

The American Cancer Society projects that about 1,400,000 new cases of cancer will be diagnosed in 2006. According to the American Cancer Society's "Cancer Facts and Figures 2006," 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 2005, the National Institutes of Health, in the American Cancer Society's "Cancer Facts & Figures 2006," estimates the overall costs of cancer to be $209.9 billion, including $74.0 billion in direct medical costs, $17.5 billion for indirect morbidity costs attributable to lost productivity due to illness and $118.4 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, liver cancer results from the spread of cancer from other places in the body to the liver. With our clinical trials, we are treating patients suffering from 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 2006," the five-year survival rate for liver cancer patients is approximately 9%, compared to the 65% 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 disease has advanced, 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 pieces 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: 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. The American Cancer Society has projected that in the United States there will be approximately 18,510 newly diagnosed cases of primary liver cancer in 2006 and it is estimated that there will be approximately 220,000 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.

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, chemotherapy, cryosurgery, percutaneous ethanol injection and radiation.

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 enable surgical removal in some of the cases which are currently inoperable by reducing the size and number of tumors sufficiently to make resection feasible. Shrinking a tumor using chemotherapy and then removing the tumor 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.

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 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 and doxorubicin, the drugs in our current clinical trials, are representative of the side-effects associated with many chemotherapy agents. Melphalan and doxorubicin 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. Doxorubicin can also cause irreversible heart tissue damage. Depending on dosage levels, the damage caused by doxorubicin can be serious and lead to congestive heart failure. The use of melphalan and doxorubicin can be fatal even when they are 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 choose only to manage the patient's discomfort from cancer with pain killers while foregoing treatment.

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 and diverted the blood flow from the liver while infusing high dosages of chemotherapy agents into the liver. A filtration circuit reduced drug concentrations before returning the diverted blood to the patient. The results were impressive but the treatment was not embraced by the medical community because it is highly invasive, resulting in prolonged recovery times, long hospital stays and very high costs. Other physicians have experimented with the delivery of chemotherapy agents to the liver by catheter, attempting to use one or more catheters to remove chemotherapy agents before they enter the general circulatory system. We are unaware of any system, however, which contains the patented attributes of the Delcath design.

Cryosurgery

Cryosurgery is the destruction of cancer cells using sub-zero temperatures in an open surgical procedure. 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, creating an ice ball. 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 an open surgical procedure;
- It involves significant complications which are similar to other open 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 as well as metastatic tumors. Patients are required to receive multiple treatments, making this option unattractive for many patients. Complications include pain and alcohol introduction to 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 withdrawn.

Radiation Therapy

Radiation therapy uses high dose x-rays to kill cancer cells. Radiation therapy is not considered an effective means of treating liver cancer and is rarely used for this purpose. Radiation is often 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. 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. This technique does not enable physicians to prescribe higher doses of chemotherapy.

Other Methods of Treatment

Still other liver cancer treatments include liver transplants, embolization, removal of tumors through the use of radio frequency waves and the use of biological response modulators, monoclonal antibodies and liposomes. The effectiveness of these treatments is limited, many have dose limiting side-effects and none is widely used.

Treatment with the Delcath System

The Delcath system is designed to address the critical shortcomings of conventional intravenous chemotherapy delivery. The Delcath system isolates the liver from the general circulatory system during liver cancer treatments with chemotherapy agents and then returns the blood exiting the liver to the general circulatory system only after the chemotherapy agent has been substantially removed by filtration outside the body. 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 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, other organs of the body receive less exposure than the liver to the chemotherapy agent. Therefore, these organs are less likely to suffer from the harmful side-effects of chemotherapy, including the cumulative harmful effect that doxorubicin has on the heart muscle.

The Delcath system kit includes the following disposable components that we purchase from third-party suppliers:

- Infusion catheter -- a thin-walled arterial infusion catheter used to deliver chemotherapy to the liver;
- Double balloon catheter -- a multi-passageway catheter used to isolate and divert the drug-laden blood exiting the liver;
- 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 -- activated carbon blood filters used to remove most of the chemotherapy agent from the isolated blood after it has flowed through the liver and before it returns to the patient's general circulation; and
- 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 infusion catheter and double balloon catheter.

The double balloon catheter has one large passageway and three smaller passageways. Each of two low-pressure balloons is inflated through one of the three 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 liver 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 inserted into the artery through which blood

normally flows to the liver. A second catheter -- the Delcath double balloon catheter -- is inserted through 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, but leaves the liver through perforations on the double balloon catheter and flows through this catheter out of the body where the infused blood is pumped through activated charcoal filters to remove most of the chemotherapy agent. The filtered blood is returned to 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. 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. Once physicians become familiar with using the Delcath system, we expect the procedure to be performed on an outpatient basis, with the patient resuming normal activities the day after the procedure is performed. We expect a patient to undergo an average of four treatments, one every three weeks. A new Delcath system kit is used for each treatment.

Integral to our research and development efforts is our program of clinical research with prominent researchers and physicians.

Our Clinical Trials

In 2005, Delcath requested a meeting 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 which allowed Delcath to submit the study under the provision of a Special Protocol Assessment ("SPA"). The FDA granted a SPA for this trial in March 2006. Under the Special Protocol and Assessment Agreement that we entered into with the FDA, a patient treated in the clinical trial as part of the 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 call for the treatment of 92 patients, equally randomized to either the Delcath treatment or "Best Available Care" as determined by the Principal Investigator. 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 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.

We intend to continue Phase III clinical trials with melphalan and doxorubicin designed to demonstrate to the FDA that administering these agents with the Delcath system to treat malignant melanoma that has spread to the liver results in better patient treatment outcomes than those obtained from administering chemotherapy agents intravenously. Phase III clinical trials are a prerequisite for FDA approval of Delcath's pre-market application. During these trials, administration of either melphalan or doxorubicin through the Delcath system must be proven to be safe and effective for the treatment of liver cancer. The FDA requires us to demonstrate that delivering either melphalan or doxorubicin using the Delcath system results in tumor responses that are better than those obtained from administering chemotherapy agents intravenously.

We expect the Phase III clinical trials using doxorubicin to be conducted at several medical centers worldwide. We have terminated the trial at the first site, the Sydney Melanoma Unit, following the evaluation of seven patients and the recruitment of four patients due to the slow pace of enrollment and the unwillingness of the medical oncologist to comply fully with the protocol. The trial protocol, which has been approved by the FDA, calls for enrolling a minimum of 122 test subjects who will be treated for malignant melanoma that has spread to the liver. Half of these test subjects will be treated with doxorubicin administered using the Delcath system and the other half, the control group, will be treated with another chemotherapy agent delivered intravenously in accord with a protocol approved by FDA. Trials will commence upon the approval of a budget by the respective institutions. However, our timetable

is subject to uncertainty and we cannot assure you that we can meet our planned schedule. We do not know whether all of the medical centers identified will be available to conduct clinical trials when we are in a position to have them commence or that we will be ready to commence the trials within any particular time period.

The FDA pre-market approval we are currently seeking is limited to administration of either melphalan or doxorubicin 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 these and other chemotherapy agents for treatment of other liver cancers and with anti-viral drugs for treatment of other diseases, such as hepatitis. 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 with another chemotherapy agent, 5-FU. These trials demonstrated that the Delcath system was capable of extracting approximately 70% to 85% of the chemotherapy agent administered to the liver. Therefore, the Delcath system permits the delivery of higher dosages of chemotherapy agents to the cancer site while at the same time minimizing damage to healthy tissue.

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

- more chemotherapy agent to the tumor site; and
- less chemotherapy agent to the general circulation than delivered by administration of the same dose by intravenous means.

In addition, clinicians involved in the Phase I and Phase II clinical trials observed:

- the safe administration of higher dosage levels of chemotherapy than those used in conventional intravenous chemotherapy delivery, and
- reduction 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.

Based on the results of our Phase I and Phase II clinical trials using doxorubicin and 5-FU, we submitted to the FDA our application for pre-marketing approval of the Delcath system as a medical device. In response to our application, the FDA 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 another 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 commits NCI to perform the research necessary under the Phase II and Phase III protocols approved by the NCI IRB with Delcath acting as the sponsor, and NCI providing the principal investigator. Delcath will provide funding to NCI in the amount of $918,750 payable in quarterly installments over the five-year term of the agreement beginning in the second quarter of 2001 unless the CRADA is terminated early. The CRADA can be terminated at any time by either party. In the event of an early termination, we would be responsible for unfunded costs incurred prior to the termination date and all reasonable termination costs. Delcath will need to negotiate a new CRADA agreement with NCI in 2006.

Research for Hepatitis Treatment

Another disease that attacks the liver is viral hepatitis. The incidence of viral hepatitis in the United States and worldwide is increasing. The long-range effects of some forms of hepatitis can include massive death of liver cells, chronic active hepatitis, cirrhosis and hepatoma. The current treatment for viral hepatitis is limited and includes long-term injections of interferon alpha, which is similar to chemotherapy in its toxicity and dosage limitations. We plan to seek a strategic partner to conduct clinical trials to determine the feasibility of using the Delcath system to administer anti-viral drugs, including interferon alpha, in the treatment of viral hepatitis. We have not entered into any arrangements, understandings or agreements with potential strategic partners.

Sales and Marketing

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 patient; and
- interventional radiologists who are members of the hospital staff and work with catheter-based systems.

Upon diagnosis of cancer, a patient is usually referred to a medical oncologist. 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, 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 and then hire a sales manager and 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, will 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 payors 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 payors, 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.

Manufacturing

We plan to utilize contract manufacturers to manufacture the components of the Delcath system. In order to maintain quality control, we plan to perform final assembly and packaging in our own facility. If we undertake these operations, our facility will be required to comply with the FDA's good manufacturing practice and quality system requirements. If we sell the Delcath system in some foreign markets, our facility will also need ISO 9000 approval from the European Union which is a required approval that European manufacturers must obtain from the International Organization for Standardization.

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. B. Braun has experience in obtaining regulatory approval for medical products in European markets and has indicated informally that it will assist us in this process. 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 located outside of the body, including the medical tubing through which a patient's blood flows and various connectors, as well as the blood filtration pump head. 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 single supplier for the activated charcoal filters used in the Delcath system. These activated charcoal filters are marketed in the U. S. for blood detoxification, but their use within the Delcath system is considered experimental under Delcath's Investigational Device Exemption (IDE) approved by the FDA.

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, and specifically the markets for systems and devices to improve the outcome of chemotherapy treatment for cancer, 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 interventional radiology and oncology communities, are important competitive factors.

The Delcath system competes with all forms of liver cancer treatments that are alternatives to resection including radiation, intravenous chemotherapy and chemotherapy through implanted infusion pumps, liver transplants, embolization, cryosurgery, radiowave ablation 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.

Many large pharmaceutical companies and research institutions are developing systems and devices to improve the outcome of chemotherapy treatment for cancer. Arrow International currently markets an implantable infusion pump, which has been successful in facilitating regional drug delivery. However, Arrow's pump lacks a means of preventing the entry of these agents into the patient's general circulation after they pass through the liver. Other companies are developing various chemotherapy agents with reduced toxicity and products to reduce the toxicity and side-effects of existing chemotherapy agents. In addition, gene therapy, vaccines and other minimally invasive procedures are currently being developed as alternatives to chemotherapy.

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 and doxorubicin, the drugs that we are initially seeking to have approved for delivery by the Delcath system, are widely used chemotherapy agents that have 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 both drugs through a mode of administration and at a dose strength that differs from those currently approved, approval for revised labeling of melphalan and doxorubicin permitting their 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. 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. Under the Federal Food, Drug, and Cosmetic Act, clinical studies for "significant risk" Class III devices require obtaining such 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.

Given the short life expectancy of patients suffering from metastatic melanoma of the liver, we believe 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 both melphalan and doxorubicin does not provide for their delivery with the Delcath system. It may be necessary to partner with the holders of an approved drug application for melphalan and doxorubicin to make this change to the labeling of both agents. We are in discussions with drug companies for this purpose, but we have no assurance that we will reach agreement with these companies or that the FDA will approve the application. If this approval is obtained, it would not have a negative effect on the manufacturers of either melphalan or doxorubicin. Rather, the drug manufacturer would have the opportunity to expand the use of the drugs as a result of changing their label to include the Delcath labeling.

Phase III clinical trial protocols using melphalan and doxorubicin have 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, conditional IRB approval at several sites and are seeking the approval of institutional review boards at additional medical centers by assembling and providing them with information with respect to the respective trials.

The approved Phase III clinical trial protocols are designed to obtain approval of both new drug labeling and a pre-market approval application providing for the use of melphalan or doxorubicin with the Delcath system. The trial protocols were 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 trials will be submitted to both of these FDA divisions.

If we successfully complete the clinical trials with both agents, we believe the manufacturers of melphalan and doxorubicin 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.	Expiration Date
Isolated perfusion method for cancer treatment	U.S. #5,069,662	October 21, 2008
Isolated perfusion device -- catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479	April 20, 2013
Device and method for isolated pelvic perfusion	U.S. #5,817,046	July 14, 2017
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841	August 30, 2016
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163	July 14, 2017
Isolated perfusion method for kidney cancer	U.S. #6,186,146	January 13, 2017
Catheter flow and lateral movement controller	U.S. #5,897,533	September 2, 2017
Method for treating glandular diseases and malignancies	Awaiting number from Patent Office	

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.

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 February 28, 2006 we had 6 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.

Item 2. Description of Property.

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.

We are not a party to any material litigation other than routine litigation incidental to our business. We believe that the outcome of any such routine litigation cannot reasonably be expected to have a material adverse effect on our business or financial condition.

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

Not applicable.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters.

Our common shares trade on the NASDAQ Small Cap market under the symbol "DCTH" and on the Boston Stock Exchange under the symbol "DCT."

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 Small Cap Market:

	Common Stock Price Range	
	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
	2004	
	High	Low
Quarter ended March 31, 2004	$4.37	$0.92
Quarter ended June 30, 2004	3.43	1.75
Quarter ended September 30, 2004	2.32	1.46
Quarter ended December 31, 2004	3.12	1.86

As of March 16, 2006, there were approximately 82 stockholders of record of our Common Stock and approximately 4,220 additional beneficial owners of our Common Stock.

Dividend Policy

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

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2005 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, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,385,800	$2.51	2,050,200
Equity compensation plans not approved by security holders	--	--	--
Total	1,385,800	$2.51	2,050,200

All other sales of equity securities by the Company during 2005 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.

Item 6. Management's Discussion and Analysis or Plan of Operation.

(a) Plan 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. The Phase I trial at the National Cancer Institute marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapeutic agent used in our initial clinical trials. 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.

During 2004, we commenced a Phase III clinical trial study of the Delcath drug delivery system for inoperable melanoma in the liver using doxorubicin and we are continuing to recruit sites worldwide.

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 clinical trials using melphalan and doxorubicin with the Delcath system and Phase II 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. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. The Company is projecting the hiring of one additional employee.

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-KSB, 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-QSB, Form 8-K and Form 10-KSB 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 7 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.

(b) Management's Discussion and Analysis of Financial Condition and Results of Operation.

Not applicable.

(c) Off-balance sheet arrangements.

We do not have any off-balance arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Item 7. Financial Statements.

Please refer to pages F-1 through F-15

Report of Independent Registered Public Accounting Firm

Balance Sheet as of December 31, 2005

Statements of Operations for the years ended December 31, 2005 and 2004 and cumulative from inception (August 5, 1988) to December 31, 2005

Statements of Stockholders' Equity for the years ended December 31, 2005 and 2004 and cumulative from inception (August 5, 1988) to December 31, 2005

Statements of Cash Flows for the years ended December 31, 2005 and 2004 and cumulative from inception (August 5, 1988) to December 31, 2005

Notes to Financial Statements

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

On April 25, 2005, Eisner LLP ("Eisner") was dismissed as the independent registered public accounting firm for the Company. On April 27, 2005, the Company retained Carlin, Charron & Rosen, LLP to act as its independent registered public accounting firm. The decision to change accountants was approved by the Audit Committee of the Company's Board of Directors.

The reports of Eisner on the balance sheets of the Company as of December 31, 2003 and 2004 and the related statements of operations, stockholders' equity and cash flows 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 did not contain any adverse opinion or disclaimer of opinion, nor were they modified as to uncertainty, audit scope or accounting principles.

In connection with the audits of the periods described above, 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 on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to Eisner's satisfaction, would have caused Eisner to make reference to the subject matter of the disagreement (s) in connection with its reports.

Item 8A. Controls and Procedures.

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

As used herein, "disclosure controls and procedures" means controls and other procedures of ours that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms issued by the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer or officers and our principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Since the date of the evaluation described above, there were no significant changes in our internal control or in other factors that could significantly affect these controls, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

We have not yet become subject to the requirement to include an annual report of management on our internal control over financial reporting in our annual reports under Section 13 or 15(d) of the Securities Exchange Act.

Item 8B. 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, 2005 that we have not previously reported.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

The information required by Items 401, 405 and 406 of Regulation S-B is incorporated by reference into this Form 10-KSB by reference to the Company's definitive proxy statement (the "Definitive Proxy Statement") for its 2006 Annual Meeting of Stockholders.

Item 10. Executive Compensation.

The information required by Item 402 of Regulation S-B is incorporated into this Form 10-KSB by reference to the Definitive Proxy Statement.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 201(d) of Regulation S-B is included in this Form 10-KSB under Item 5. The information required by Item 403 of Regulation S-B is incorporated into this Form 10-KSB by reference to the Definitive Proxy Statement.

Item 12. Certain Relationships and Related Transactions.

The information required by Item 404 of Regulation S-B, if any, is incorporated into this Form 10-KSB by reference to the Definitive Proxy Statement.

Item 13. Exhibits

(a) Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc., as amended to June 16, 2004. (incorporated by reference to Exhibit 3(i) to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (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 Series A Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.5	Form of Series C Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.6	Form of Series D Warrant to Purchase Shares of Common Stock dated as of December 7, 2004 (incorporated by reference to Exhibit 4.10 to

Exhibit No.	Description
	Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
4.7	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)).
4.8	Form of 2005 Series B 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 4.2 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 011-16133)).
4.9	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	1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.2	1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.3	2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.4	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)).
10.5	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)).
10.6	Employment Agreement, between the Company and M. S. Koly, as amended by Amendment No. 1 thereto (incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.7	Employment Agreement, effective as of October 1, 2003, by and among Delcath Systems, Inc. and Samuel Herschkowitz (incorporated by reference to Exhibit 10.6 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2003 (Commission File No. 001-16133)).
10.8	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)).
10.9	Registration Rights Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Schedule I thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K dated March 19, 2004 (Commission File No. 001-16133)).
10.10	Common Stock Purchase Agreement dated as of November 24, 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 November 24, 2004 (Commission File No. 001-16133)).

Exhibit No.	Description
10.11	Registration Rights Agreement dated as of November 24, 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 November 24, 2004 (Commission File No. 001-16133)).
10.12	Common Stock Purchase Agreement dated as of December 7, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Exhibit A thereto (incorporated by reference to Exhibit 10.5 to Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
10.13	Registration Rights Agreement dated as of December 7, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Schedule I thereto (incorporated by reference to Exhibit 10.6 to Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
10.14	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)).
10.15	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)).
10.16	Voting Agreement dated as of November 27, 2005 by and between Delcath Systems, Inc. and the purchasers listed on Exhibit A to the Common Stock Purchase Agreement dated November 27, 2005 and Vertical Ventures LLC (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).
10.17	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)).
10.18	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)).
10.19	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)).
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.

Item 14. Principal Accountant Fees and Services.

The information required by Item 9(e) of Schedule 14A is incorporated into this Form 10-KSB by reference to the Definitive Proxy Statement.

Signatures

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DELCATH SYSTEMS, INC.
Registrant

/s/ M. S. KOLy

M. S. Koly, President
March 31, 2006

Each person whose signature appears below appoints M. S. Koly as his attorney-in-fact, with full power of substitution and resubstitution to sign any and all amendments to this report on Form 10-KSB 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.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ M. S. KOLY M. S. Koly	President, Chief Executive Officer, Treasurer and Director (Principal Executive Officer)	March 31, 2006
/s/ PAUL M. FEINSTEIN Paul M. Feinstein	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2006
/s/ SAMUEL HERSCHKOWITZ. M.D. Samuel Herschkowitz, M.D.	Chairman of the Board, Non-Officer	March 31, 2006
/s/ MARK A. CORIGLIANO Mark A. Corigliano	Director,	March 31, 2006
/s/ DANIEL ISDANER Daniel Isdaner	Director	March 31, 2006
/s/ VICTOR NEVINS Victor Nevins	Director	March 31, 2006

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc., as amended to June 16, 2004. (incorporated by reference to Exhibit 3(i) to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (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 Series A Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.5	Form of Series C Warrant to Purchase Shares of Common Stock dated as of November 24, 2004 (incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K dated November 24, 2004 (Commission File No. 001-16133)).
4.6	Form of Series D Warrant to Purchase Shares of Common Stock dated as of December 7, 2004 (incorporated by reference to Exhibit 4.10 to

Exhibit No.	Description
	Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
4.7	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)).
4.8	Form of 2005 Series B 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 4.2 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 011-16133)).
4.9	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	1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.2	1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.3	2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
10.4	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)).
10.5	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)).
10.6	Employment Agreement, between the Company and M. S. Koly, as amended by Amendment No. 1 thereto (incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.7	Employment Agreement, effective as of October 1, 2003, by and among Delcath Systems, Inc. and Samuel Herschkowitz (incorporated by reference to Exhibit 10.6 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2003 (Commission File No. 001-16133)).
10.8	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)).
10.9	Registration Rights Agreement dated as of March 19, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Schedule I thereto (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K dated March 19, 2004 (Commission File No. 001-16133)).
10.10	Common Stock Purchase Agreement dated as of November 24, 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 November 24, 2004 (Commission File No. 001-16133)).

Exhibit No.	Description
10.11	Registration Rights Agreement dated as of November 24, 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 November 24, 2004 (Commission File No. 001-16133)).
10.12	Common Stock Purchase Agreement dated as of December 7, 2004 by and among Delcath Systems, Inc. and the Purchasers Listed on Exhibit A thereto (incorporated by reference to Exhibit 10.5 to Registrant's Registration Statement on Form S-3 (Registration No. 333-121681)).
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10.16	Voting Agreement dated as of November 27, 2005 by and between Delcath Systems, Inc. and the purchasers listed on Exhibit A to the Common Stock Purchase Agreement dated November 27, 2005 and Vertical Ventures LLC (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K dated November 28, 2005 (Commission File No. 001-16133)).
10.17	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)).
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23	Consent of Carlin, Charron & Rosen.
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.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage company) as of December 31, 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2005 and for the period from August 5, 1988 (inception) to December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referenced above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage company) as of December 31, 2005, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2005 and for the period from August 5, 1988 (inception) to December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

/s/ Carlin, Charron & Rosen, LLP

Glastonbury, CT
March 24, 2006

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Balance Sheet

	December 31, 2005
Assets	
Current assets	
Cash and cash equivalents	$ 1,704,131
Certificates of deposit	11,097,790
Interest receivable	91,574
Prepaid insurance	26,917
Total current assets	12,920,412
Property and equipment, net	7,554
Total assets	$ 12,927,966
Liabilities and Stockholders' Equity	
Current liabilities	
Accounts payable and accrued expenses	$ 330,070
Total current liabilities	330,070
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; 18,877,753 shares issued and 18,849,653 outstanding	188,497
Additional paid-in capital	38,244,566
Deficit accumulated during development stage	(25,835,167)
Total stockholders' equity	12,597,896
Total liabilities and stockholders' equity	$ 12,927,966

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Statements of Operations

	Year ended December 31,		Cumulative from inception (August 5, 1988) to
	2005	2004	December 31, 2005
Costs and expenses			
General and administrative expenses	$ 1,367,344	$ 1,059,815	$ 8,439,205
Research and development costs	1,744,251	2,306,733	17,059,480
Total costs and expenses	3,111,595	3,366,548	25,498,685
Operating loss	(3,111,595)	(3,366,548)	(25,498,685)
Other income (expense)			
Interest income	246,976	100,216	1,333,596
Interest expense	--	--	(171,473)
Net loss	$ (2,864,619)	$ (3,266,332)	$ (24,336,562)
Common share data			
Basic and diluted loss per share	$ (0.18)	$ (0.28)	
Weighted average number of basic and diluted common shares outstanding	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, 2005 and 2004 and
cumulative from inception (August 5, 1988) to December 31, 2005

	Common stock $.01 par value					
	Issued		In treasury		Outstanding	
	No. of shares	Amount	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988	621,089	$ 6,211	--	$ --	621,089	$ 6,211
Sale of preferred stock, August 22, 1988	--	--	--	--	--	--
Shares returned due to relevant technology milestones not being fully achieved, March 8, 1990	--	--	(414,059)	(4,141)	(414,059)	(4,141)
Sale of stock, October 2, 1990	--	--	17,252	173	17,252	173
Sale of stock (common stock at $7.39 per share and Class B preferred stock at $2.55 per share), January 23, 1991	--	--	46,522	465	46,522	465
Sale of stock, August 30, 1991	--	--	1,353	14	1,353	14
Sale of stock, December 31, 1992	--	--	103,515	1,035	103,515	1,035
Sale of stock (including 10,318 warrants, each to purchase one share of common stock at $10.87), July 15, 1994	--	--	103,239	1,032	103,239	1,032
Sale of stock, December 19, 1996	--	--	39,512	395	39,512	395
Shares issued (including 78,438 warrants each to purchase one share of common stock at $10.87) in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984	156,879	1,569
Sale of stock, December 31, 1997	53,483	535	--	--	53,483	535
Exercise of stock options	13,802	138	3,450	35	17,252	173
Shares issued as compensation for consulting services valued at $10.87 per share based on a 1996 agreement	2,345	23	828	8	3,173	31
Shares issued in connection with exercise of warrants	21,568	216	--	--	21,568	216
Sale of stock, January 16, 1998	34,505	345	--	--	34,505	345
Sale of stock, September 24, 1998	3,450	35	--	--	3,450	35
Shares returned as a settlement of a dispute with a former director at $1.45 per share, the price originally paid, April 17, 1998	(3,450)	(35)	--	--	(3,450)	(35)
Exercise of stock options	8,626	86	--	--	8,626	86
Sale of stock (including 5,218 warrants each to purchase one share of common stock at $14.87), June 30, 1999	46,987	470	--	--	46,987	470
Shares issued in connection with exercise of warrants	2,300	23	--	--	2,300	23
Sale of stock, April 14, 2000	230,873	2,309	--	--	230,873	2,309
Dividends paid on preferred stock	690,910	6,909	--	--	690,910	6,909
Conversion of preferred stock	833,873	8,339	--	--	833,873	8,339
Sale of stock (including 1,200,000 warrants each to purchase one share of common stock at $6.60), October 19, 2000	1,200,000	12,000	--	--	1,200,000	12,000
Shares issued as compensation for stock sale	85,000	850	--	--	85,000	850
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)	--	--	(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	--	--	243,181	2,432
Repurchases of stock, November and December 2002			(28,100)	(281)	(28,100)	(281)
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	--	--	3,895,155	38,952
Proceeds from sale of unit option	--	--	--	--	--	--
Exercise of 2003 Warrants	1,730,580	17,305	--	--	1,730,580	17,305

Deficit accumulated from inception to December 31, 2003	--	--	--	--	--	--
Balance at December 31, 2003	9,772,732	$ 97,727	(28,100)	$ (281)	9,744,632	97,446
Sale of stock, March, 2004	1,197,032	11,970	--	--	1,197,032	11,970
Exercise of 2002 Warrants	20,265	203	--	--	20,265	203
Sale of stock, April, 2004	290,457	2,905	--	--	290,457	2,905
Stock options issued as compensation	--	--	--	--	--	--
Sale of stock, November, 2004	1,069,520	10,695	--	--	1,069,520	10,695
Sale of stock, December, 2004	236,966	2,370	--	--	236,966	2,370
Exercise of 2003 Warrants	2,160,163	21,602	--	--	2,160,163	21,602
Exercise of 2003 Representative's Unit Warrants	282,025	2,820	--	--	282,025	2,820
Exercise of Representative's Common Stock Warrants	152,025	1,520	--	--	152,025	1,520
Exercise of stock options	62,000	620	--	--	62,000	620
Net Loss	--	--	--	--	--	--
Balance at December 31, 2004	15,243,185	$ 152,432	(28,100)	$ (281)	15,215,085	$ 152,151
Exercise of 2003 Representative's Unit Warrants	42,180	422	--	--	42,180	422
Exercise of Representative's Common Stock Warrants	157,180	1,572	--	--	157,180	1,572
Exercise of stock options	597,000	5,970	--	--	597,000	5,970
Stock options issued as compensation	--	--	--	--	--	--
Exercise of 2004 Warrants	1,107,313	11,073	--	--	1,107,313	11,073
Exercise of 2005 Warrants	940,957	9,410	--	--	940,957	9,410
Sale of stock, November, 2005	753,013	7,530	--	--	753,013	7,530
Shares issued as compensation	36,925	369	--	--	36,925	369
Net Loss	--	--	--	--	--	--
Balance at December 31, 2005	18,877,753	$ 188,778	(28,100)	$ (281)	18,849,653	$ 188,497

	Preferred Stock		Class A preferred stock		Class B preferred stock	
	$.01 par value		$.01 par value		$.01 par value	
	No. of shares	Amount	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	--	--	--	--	416,675	4,167
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 common stock at $14.87), June 30, 1999	--	--	--	--	--	--
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)	(416,675)	(4,167)
Sale of stock (including 1,200,000 warrants each to purchase one share of common 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	--	--	--	--	--	--
Deficit accumulated from inception to December 31, 2003	--	--	--	--	--	--
Balance at December 31, 2003	--	$ --	--	$ --	--	$ --
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	--	--	--	--	--	--
Net Loss	--	--	--	--	--	--
Balance at December 31, 2004	--	$ --	--	$ --	--	$ --
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	--	$ --	--	$ --	--	$ --

	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	9,987	--	10,001
Sale of stock, December 31, 1992	1,013,969	--	1,015,004
Sale of stock (including 10,318 warrants, 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
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
Deficit accumulated from inception to December 31, 2003	--	(18,205,511)	(18,205,611)
Balance at December 31, 2003	$ 21,777,065	$ (19,704,216)	$ 2,170,295
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
Net Loss	--	(3,266,332)	(3,266,332)
Balance at December 31, 2004	$ 29,605,543	$ (22,970,548)	$ 6,787,146
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	--	2,310,002
Shares issued as compensation	103,056	--	103,425
Net Loss	--	(2,864,619)	(2,864,619)
Balance at December 31, 2005	$ 38,244,567	$ (25,835,167)	$ 12,597,897

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31,		Cumulative from inception (August 5, 1988) to
	2005	2004	December 31, 2005
Cash flows from operating activities:			
Net loss	$ (2,864,619)	$ (3,266,332)	$ (24,336,562)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	8,270	5,222	2,533,662
Stock and warrant compensation expense issued for consulting services	103,425	--	339,711
Depreciation expense	6,052	5,526	37,744
Amortization of organization costs	--	--	42,165
Rent expense attributable to lease deposit	--	24,000	--
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	20,899	(316)	(26,917)
Increase in interest receivable	(58,688)	(18,614)	(91,574)
(Decrease) increase in accounts payable and accrued expenses	(234,556)	304,426	330,070
Net cash used in operating activities	(3,019,217)	(2,946,088)	(21,171,701)
Cash flows from investing activities			
Purchase of furniture and fixtures	--	(5,345)	(45,298)
Purchase of short-term investments	(11,097,790)	(6,052,383)	(22,067,494)
Proceeds from maturities of short-term investments	7,055,129	1,014,575	10,969,704
Organization costs	--	--	(42,165)
Net cash used in investing activities	(4,042,661)	(5,043,153)	(11,185,253)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	8,563,674	7,877,961	32,906,759
Repurchases of common stock	--	--	(51,103)
Dividends paid	--	--	(499,535)
Proceeds from short-term borrowings	--	--	1,704,964
Net cash provided by financing activities	8,563,674	7,877,961	34,061,085
Increase (decrease) in cash and cash equivalents	1,501,796	(111,280)	1,704,131
Cash and cash equivalents at beginning of period	202,335	313,615	--
Cash and cash equivalents at end of period	$ 1,704,131	$ 202,335	$ 1,704,131
Cash paid for interest	$ --	$ --	$ 171,473
Supplemental non-cash activities:			
Conversion of debt to common stock	$ --	$ --	$ 1,704,964
Common stock issued for preferred stock dividends	$ --	$ --	$ 999,070
Conversion of preferred stock to common stock	$ --	$ --	$ 24,167
Common stock issued as compensation for stock sale	$ --	$ --	$ 510,000

See accompanying notes to financial statements.

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

December 31, 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 doxorubicin and melphalan, chemotherapeutic agents, 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 $37,744 at December 31, 2005. Depreciation expense for the years ended December 31, 2005 and 2004 was $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

The Company has historically accounted for its employee stock option plans in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation cost is measured on the date of grant only if the fair market value of the underlying stock on the date of grant exceeded the exercise price. Fair market values of the Company's Common Stock at the dates options were granted, prior to the Company's stock becoming publicly traded, were based on third party sales of stock at or around the dates options were granted or, in the absence of such transactions, based on a determination by the board of directors based on current available information. Such cost is then recognized over the period the recipient is required to perform services to earn such compensation. If a stock option does not become vested because an employee fails to fulfill an obligation, the estimate of compensation expense recorded in previous periods is adjusted by decreasing compensation expense in the period of forfeiture.

The Company has adopted Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure in accordance with the provisions of SFAS No. 123.

Had compensation cost for the Company's stock option grants been determined based on the fair value at the grant dates consistent with the methodology of SFAS No. 123, the Company's net loss and net loss per share for the years ended December 31, 2005 and 2004 would have been increased to the pro forma amounts indicated as follows:

	2005	2004
Net loss	$ (2,886,619)	$ (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 stock options granted in July 2005 was $.58 estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumption of a risk free interest rate of 3.77% and volatility of 41% while the per share weighted average fair value of stock options granted in November, 2005 using the Black-Scholes option-pricing model was $.66 with the weighted average assumption of a risk free interest rate of 4.45% and a volatility of 35%.

(f) Net Loss Per Common Share

For the years ended December 31, 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 December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment." SFAS No. 123 (revised 2004) requires companies to recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation. That cost will be recognized over the period during which an employee is required to provide service in exchange for the award, usually the vesting period. Subsequent changes in fair value during the requisite service period, measured at each reporting date, will be recognized as compensation cost over that period. SFAS No. 123 (revised 2004) is effective in the first interim or annual period beginning after June 15, 2005. The Company will be required to adopt SFAS No. 123 (revised 2004) in 2006. The Company is currently evaluating the impact of the adoption of SFAS 123 (revised 2004) on the Company's financial position and results of operations.

In December 2005, the FASB issued SFAS No. 155, "Accounting for Certain Hybrid Financial Instruments - an amendment to FASB Statements No. 133 and 140" and in May 2005, the FASB issued SFAS No. 154 "Accounting and Error Corrections - a replacement of APB opinion No. 20 and FASB Statement No. 3." The Company is not significantly impacted by these statements and does not expect their implementation to have a material impact on the Company's financial statements.

(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 to purchase from the Company one share of Common Stock, at a price of $5.00 per share, subject to adjustment (the "Purchase Price") 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 Securites Act of 1933.

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 Securites 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 institutional and accredited investors. 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 Securites 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, trading therein has ceased.

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 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 are $8,270 and $5,222, respectively.

During 2005, the Company received net proceeds of $2,894,491 as 1,069,526 of the November 2004 Warrants were exercised and 37,787 of the March 2004 Warrants were exercised for which it 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 would be 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 and trading therein has ceased.

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.

(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 an Incentive Stock Option Plan, a Non-Incentive Stock Option Plan, 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 the options shall be granted as well as the terms and conditions of each option grant, the option price and the duration of each option.

The Company's Incentive and Non-Incentive Stock Option Plans were approved and became effective on November 1, 1992. 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 2005 and 2004 is as follows:

	The Plans			
	Stock Options	Exercise Price Per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2003	1,520,684	$0.60 - $4.93	$2.09	2.92
Exercised	(62,000)	$0.71 - $1.03	.72	
Expired	(441,664)	$2.90 - $4.93	4.14	
Outstanding at December 31, 2004	1,017,020	$0.60 - $3.31	1.28	2.72
Granted	967,500	$2.78 - $3.59	3.20	
Expired	(1,720)	$3.31	3.31	
Exercised	(597,000)	$0.60 - $1.03	.89	
Outstanding at December 31, 2005	1,385,800	$.71 - $3.59	$2.51	4.17

At December 31, 2005, 2004, and 2003 options for 394,300, 737,520, and 935,678 shares, respectively, were exercisable at a weighted average exercise price of $1.89, $1.30, and $2.79 per share, respectively.

(d) Warrants

A summary of warrant activity is as follows:

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
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	
Exercised	(2,247,624)	$1.02 - 3.01	$ 2.55	
Expired	(825,763)	$2.75 - 10.50	$ 7.01	
Outstanding at December 31, 2005	2,170,961	$1.02 - 3.91	$ 3.14	3.27

(3) Income Taxes

As of December 31, 2005, the Company had net operating loss carryforwards for federal income tax purposes of approximately $21,420,000. A portion of that amount, $13,420,000, 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 $8,000,000 is available to offset future federal taxable income, if any, ratably through 2025. The available net operating loss carryforwards after applying the annual limitation under Section 382 resulted in a deferred tax asset of approximately $3,473,000 at December 31, 2005 ($2,295,000 at December 31, 2004). Management does not expect the Company to have taxable income in the near future and established a 100% valuation allowance against the deferred tax asset created by the available net operating loss carryforwards at December 31, 2005 and 2004. The valuation allowance increased $1,178,000 during the year ended December 31, 2005, and increased $1,015,000 during the year ended December 31, 2004.

(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, 2005 and 2004.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-114600, 333-121681 and 333-130872) and the Registration Statement on Form S-8 (No. 333-119898) of Delcath Systems, Inc. of our report dated March 24, 2006, relating to the financial statements which appear in this Annual Report on Form 10-KSB.

/s/ Carlin, Charron & Rosen, LLP

Glastonbury, Connecticut
March 31, 2006

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14

I, M. S. Koly, certify that:

1. I have reviewed this annual report on Form 10-KSB of DELCATH SYSTEMS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to

adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 31, 2006

/s/ M. S. KOLY

M. S. Koly
Chief Executive Officer
(Principal executive officer)

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14

I, Paul M. Feinstein, certify that:

1. I have reviewed this annual report on Form 10-KSB of DELCATH SYSTEMS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to

adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 31, 2006

/s/ PAUL M. FEINSTEIN

Paul M. Feinstein
Chief Financial Officer
(Principal financial officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-KSB for the year ended December 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, M. S. Koly, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ M. S. KOLY

M. S. Koly Chief Executive Officer

March 31, 2006

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-KSB for the year ended December 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul M. Feinstein, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ PAUL M. FEINSTEIN

Paul M. Feinstein
Chief Financial Officer

March 31, 2006