DELCATH SYSTEMS INC
Form 10KSB
March 30, 2004

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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, 2003

[ ] 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.
(Exact name of Small Business Issuer as specified 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	06905
(Address of principal executive offices)	(Zip Code)

203-323-8668
(Issuer's telephone number, including area code)

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

Title of Each Class	Name of Each Exchange On Which Registered
Common Stock, par value $.01 per share	Boston Stock Exchange
Redeemable Common Stock Warrants issued in 2000	Boston Stock Exchange
2003 Redeemable Common Stock Purchase Warrants	Boston Stock Exchange

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

Common Stock, par value $0.01 per share
Redeemable Common Stock Warrants issued in 2000
2003 Redeemable Common Stock Purchase Warrants

Check whether the Issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B in this form, and no disclosure will be contained, to the best of the Issuer'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. [ ]

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 $1.71 per share, was $16,687,260 as of February 28, 2004.

At February 28, 2004, the registrant had outstanding 9,758,632 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for 2004 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.)	Incorporated into Part III of this Form 10-KSB

Transitional Small Business Disclosure Format (check one):

Yes [ ] No [X]

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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 and to administer chemotherapy and other therapeutic agents directly to the liver. Since our inception, we have raised approximately $19.2 million in funds (net of fundraising expenses), and we have invested approximately $13.0 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, and it cannot be marketed in the United States without FDA pre-marketing approval. We plan to conduct 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 a particular chemotherapy agent, doxorubicin, currently used to treat malignant melanoma that has spread to the liver. We also plan to continue our clinical trial for the use of the Delcath system with another chemotherapy agent, melphalan, which is also currently used against a variety of cancers that originate in or have spread to the liver. Additionally, we plan to continue 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-marketing approval for use of the Delcath system with doxorubicin to treat malignant melanoma that has spread to the liver. Our highest priority is completing the Phase III clinical trials, 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 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 other forms of liver cancer using other chemotherapy agents and treatment of hepatitis using anti-viral drugs. In August 2001, we commenced a Phase I clinical trial at the National Cancer Institute using melphalan, a chemotherapy agent. 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 will depend on our ability to establish strategic alliances with pharmaceutical manufacturers or other strategic partners in conjunction with our research into other therapeutic compounds and to raise additional funds for these purposes. Additional FDA pre-marketing approval 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, France, Germany, Italy and Spain, have a higher incidence of liver cancer than the United States. Additionally, Australia has been cited as having the highest incidence of skin cancer in the world. Given that our current Phase III clinical trials are with a chemotherapy agent that is used to treat malignant melanoma that has spread to the liver, upon obtaining FDA pre-marketing approval, we intend to target the

Australian market. We also 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 1,368,000 new cases of cancer will be diagnosed in 2004. According to the American Cancer Society's "Cancer

Facts and Figures 2004," cancer remains the second leading cause of death in the United States exceeded only by heart disease. While researchers continue to develop innovative new treatments for some forms of this disease, surgical resection, chemotherapy, radiation and hormone therapy continue to be the most commonly used treatments.

The financial burden of cancer is great for patients, their families and society. The National Institutes of Health, in the American Cancer Society's "Cancer Facts & Figures 2004," estimates the overall costs of cancer in the year 2003 to be $189.5 billion, including $64.2 billion in direct medical costs, $16.3 billion for indirect morbidity costs attributable to lost productivity due to illness and $109 billion for indirect mortality costs attributable to lost productivity due to 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 initial Phase III clinical trials, we will seek to develop data on metastatic melanoma which has spread to the liver. According to the American Cancer Society's "Cancer Facts & Figures 2004," the five-year survival rate for liver cancer patients, both primary and secondary, is approximately 6.9%, compared to the 63% for all other forms of cancer combined. 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, more than 80% of cancerous liver tumors cannot be surgically removed at the time of diagnosis. A significant number of patients 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 The World Health Report 2003, liver cancer is the fourth most common form of cancer worldwide, accounting for 619,000 deaths. The American Cancer Society in its "Cancer Facts & Figures 2004" has projected that in the United States there will be approximately 18,920 newly diagnosed cases of liver cancer, and 55,100 new cases of melanoma in 2004.

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 80% 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. After resection, chemotherapy can be administered through the Delcath system 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 doxorubicin, the drug we are seeking to have approved for use in the Delcath system, are representative of the side-effects associated with many chemotherapy agents. Doxorubicin causes irreversible heart tissue damage. Depending on dosage levels, the damage caused by doxorubicin can be serious and lead to congestive heart failure. Doxorubicin can also cause severe mucositis leading to ulceration of the mouth and digestive organs, damage to a patient's immune system through destruction of bone marrow cells, as well as acute nausea, severe vomiting, dermatological problems and hair loss. The use of doxorubicin can be fatal even when it is 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 developed a procedure in which he surgically 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 treatment, however, 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.

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 system involves a series of three catheter insertions, each of which is made through the skin. During 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 of 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 Phase I and Phase II clinical trials, patients remained 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 that is being conducted presently at The National Cancer Institute and was previously conducted at Yale University, M.D. Anderson Cancer Center and other prominent medical institutions.

Our Clinical Trials

We intend to conduct Phase III clinical trials designed to demonstrate to the FDA that administering doxorubicin with the Delcath system to treat malignant melanoma that has spread to the liver results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously. Phase III clinical trials are a prerequisite for FDA approval of Delcath's pre-marketing application. During these trials, administration of 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 doxorubicin using the Delcath system results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously.

We expect the Phase III clinical trials to be conducted at several medical centers worldwide. 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.

We have received approval from the Therapeutics Goods Administration, Australia's equivalent of the U.S. FDA, to commence a Phase III trial at the Sydney Melanoma Unit in Australia. We have agreed on a budget for the trial, and we expect to recruit suitable patients. These trials have recently been started. The Sydney Melanoma Unit is the clinical unit of the Department of Surgery of the University of Sydney. It was formed in 1968 and is the largest treatment center for malignant melanoma in the world and conducts a wide range of basic and clinical research relating to melanoma. The Unit has a worldwide reputation for the quality of its patient care, research and treatment programs. Omnicare Clinical Research has been hired as the contract research organization ("CRO") to conduct these trials. Similarly, we intend to hire a CRO to conduct trials at an appropriate domestic research facility. The CRO represents the clinical trial sponsor. They ensure that the principal investigator follows the established protocol and collects the clinical data. The CRO and principal investigators conducting the clinical trials are not our employees. As a result, we have limited control over their activities and can expect that only limited amounts of their time will be dedicated to our clinical trials. They may fail to meet their contractual obligations or fail to meet regulatory standards in the performance of their obligations, and we may not be able to prevent or correct their failures. Failure of the CRO to perform as expected or required, including failure of the principal investigators to enroll a sufficient number of patients for our trials, could result in the failure of the clinical trials and the failure to obtain FDA pre-marketing approval. We believe that we will acquire sufficient data to seek FDA pre-marketing approval of the Delcath system within twelve to eighteen months after the last patient enrolled.

We do not know how long the FDA may take to evaluate our submission, and they may require that additional trials be conducted or they may not grant approval.

The FDA pre-marketing approval we are currently seeking is limited to

administration of 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-marketing approvals for using the Delcath system with 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-marketing 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 three United States medical centers under investigational device and investigational new drug exemptions granted by the FDA. The trials were designed to demonstrate the system's "functionality," or its ability to administer to and extract from the liver approved and marketed chemotherapy agents. Forty-four patients participated in the trials. Twenty-one of these test subjects had primary liver cancer or melanoma which had spread to the liver and were treated with doxorubicin. The remaining

twenty-three test subjects suffered from other forms of liver cancer and/or were treated 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:

- reduction in tumor size; and
- the safety of the system at higher dosage levels of chemotherapy than those used in conventional intravenous chemotherapy delivery.

Further, though not demonstrated in a statistically significant manner because of the limited number of patients tested, clinicians observed 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, 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 application to change the labeling must be filed by a drug manufacturer holding an existing new drug application or an abbreviated new drug application. We have reached a preliminary verbal understanding with a drug manufacturer holding an existing license for doxorubicin to submit an application to the FDA supporting the new labeling based on data from the Phase III clinical trial. The pre-marketing approval and drug relabeling applications must demonstrate the clinical utility of a particular drug when administered through the Delcath system. To do so, we must demonstrate, in a statistically meaningful manner, that administering chemotherapy agents with the Delcath system results in survival times of patients that are longer than those obtained from administering chemotherapy agents intravenously.

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 completed its recruitment of patients, all experiencing metastatic and unresectable liver cancer. The goal of a Phase I clinical trial is to determine the maximum tolerated dose of melphalan that can be administered before it becomes toxic to the patient's system. H. Richard Alexander, MD, chief of the Surgical Metabolism Section at NCI has drafted a Phase II study protocol on the basis of toxicity profiles and efficacy responses observed thus far. This protocol is expected to focus on specific patient populations, including patients with melanoma and colorectal cancers that have metastasized to the liver. In preparation for the protocol's filing, the Company has collected data from the majority of treated patients including pharmacokinetics of the high-dose melphalan therapy, responses documented on patient CT scans and the observed side effects. The Company is analyzing this data in preparation for a meeting with the FDA to discuss the Phase II protocol and to discuss the possibility of obtaining accelerated approval from the FDA.

These clinical trials are subject to the terms and conditions of the Cooperative Research and Development Agreement (the "CRADA") between us and NCI. We obtained FDA approval to conduct the Phase I clinical trial; however, further FDA approval is necessary to conduct Phase II studies. We have not yet requested such approval. The goal of a Phase II clinical trial is to determine various factors such as the appropriate dosage, the timing of each dose and the efficacy of the proposed dose. We cannot estimate how long it will be until we receive FDA approval

to commence the Phase II study. The scope of the Phase II study is to develop a Delcath system-based treatment protocol for the regional therapy of the liver using escalating doses of melphalan delivered through the utilization of the Delcath system and to develop a Delcath system-based Phase II treatment protocols as a follow-up to the Phase I study. The Phase II study will involve patients with specific histologies (diseases) who have unresectable cancers

confined to the liver using the maximum tolerated dose of melphalan administered using the Delcath system.

The patients will be treated with up to four series of infusions based upon toxicity and response to treatment. The Phase II study is expected to begin shortly after completion of the Phase I.

The CRADA commits NCI to perform the research necessary under the Phase I and Phase II protocols approved by the FDA 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. The term of the CRADA is intended to allow for what the parties expect to be the potential maximum amount of time necessary to complete and evaluate Phase I and Phase II trials. An amendment to the CRADA would be necessary if the parties decide to initiate additional clinical trials using another chemotherapy agent. If the results of the Phase I and Phase II trials are successful, we will probably need additional capital to pay for the expenses associated with a Phase III clinical trial.

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 including the Sydney Melanoma Unit. 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 against the control group a statistically measurable increase in life expectancy for the kinds of cancers treated at a cost effective price;
- 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.

Nissho Agreement

In December 1996, we entered into an agreement with Nissho Corporation, a large manufacturer and distributor of medical devices and pharmaceuticals based in Osaka, Japan which grants to Nissho the exclusive right to distribute the Delcath system in Japan, China, Korea, Hong Kong and Taiwan until December 31, 2004. Nissho, at that time, invested $1,000,000 in Delcath.

Products covered by the agreement include the Delcath system for the treatment of cancer in the liver and the lower extremities, as well as new products that may be added by mutual agreement. Nissho is required to purchase products from Delcath in connection with clinical trials and for resale in its market at prices to be determined by mutual agreement. Nissho has agreed, in its territory, not to engage in the business of manufacturing, distributing or selling systems similar to the Delcath system for the liver or other organs or body regions.

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. Each treatment with the Delcath system, including the cost of the treatment kit, has an estimated cost of approximately $12,000, resulting in a total estimated treatment cost of approximately $48,000. This compares to a total estimated cost of conventional aggressive chemotherapy treatment of approximately $160,000 to $180,000, which includes the hospitalization and treatment costs associated with the side-effects of the systemic delivery of chemotherapy agents.

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.

To date, we have purchased the activated charcoal filters used in the Delcath system from Asahi Medical Products of Japan. Asahi has discontinued manufacturing these filters. We have an inventory of filters from Asahi which we expect will be sufficient to meet our needs for at least the next twelve months. However, as part of our application process with the FDA, we obtained approval

to utilize filters from any manufacturer that falls within certain performance parameters and meets the specifications on file with the FDA. Therefore, we are currently testing an alternative filter from a domestic manufacturer that we believe is capable of providing us with the quality of filters that are required to meet the specifications on file with the FDA in the quantity that we will require to conduct future clinical trials and to market the Delcath system commercially.

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, including Merck & Co., Inc., are developing various chemotherapy agents with reduced toxicity, while other companies are developing products to reduce the toxicity and side-effects of chemotherapy treatment. 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-marketing application prior to commercial distribution.

Doxorubicin, the drug that we are initially seeking to have approved for delivery by the Delcath system, is a widely used chemotherapy agent that has been approved by the FDA. Melphalan, the drug that will be administered through the Delcath system in the NCI-sponsored study, is a chemotherapy agent that has also 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 doxorubicin and melphalan products permitting their use with the Delcath system must be obtained. The application to change the labeling must be filed by a drug manufacturer holding an existing new drug application or an abbreviated new drug application. We are currently in discussions with a drug manufacturer who holds an existing license for doxorubicin for the manufacturer to submit an application supporting the new labeling, assuming data from the Phase III clinical trial is favorable. We are also currently in discussions with the drug manufacturers that hold a new drug application or an abbreviated new drug application for melphalan and plan actively to solicit one of them to file an application for new labeling with the FDA.

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, fire hazard control 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-marketing 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-marketing 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 of 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 doxorubicin and melphalan does not provide for its delivery with the Delcath system. We must partner with the holders of an approved drug application for doxorubicin and melphalan 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 doxorubicin or melphalan. 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 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 approval from each investigational site that will conduct the trials. We have received institutional review board approval at the Sydney Melanoma Unit and are seeking the approval of institutional review boards at several other medical centers by assembling and providing them with information with respect to the trials.

The FDA requires that, in order to obtain approval to re-label doxorubicin for delivery using the Delcath system, we demonstrate that delivering doxorubicin using the system results in patient survival times that are longer than those obtained from administering chemotherapy agents intravenously.

The approved Phase III clinical trial protocols are designed to obtain approval of both new drug labeling and a pre-marketing approval application providing for the use of 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. The foregoing facts will also apply if our clinical trial using melphalan is successful in Phases I, II and III.

If we successfully complete the clinical trials with both agents, we believe the manufacturers of doxorubicin and melphalan will submit to the FDA an application to deliver the agent to the liver through the Delcath system. Under the Food, Drug and Cosmetic Act, the Delcath system cannot be marketed until the new drug application, or supplemental new drug application and the pre-marketing 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. 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-marketing approval or clearance.

In April 1996, legislation was enacted that permits a medical device which requires FDA pre-marketing 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 the European Community, we must obtain a CE mark, which is the official marking required by the European Community for all electric and electronic equipment that will be sold anywhere in the European Union, except for limited use as a clinical trial device. Supplemental device approvals also might be required to market and sell the Delcath system.

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 six United States patents, as well as three corresponding foreign patents in Canada, Europe and Japan that we believe are or may be material to our business:

Summary Description of Patents	Patent No.	
Isolated perfusion method for cancer treatment	U.S. #5,069,662	O
Isolated perfusion device -- catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479	A
Device and method for isolated pelvic perfusion	U.S. #5,817,046	J
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841	A
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163	J
Isolated perfusion method for kidney cancer	U.S. #6,186,146	J

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, 2003 we had 5 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 there can be no assurance that additional facilities and equipment will be available upon 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 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 and Small Business Issuer Purchase of Equity Securities.

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 redeemable common stock purchase warrants we issued in 2000 are listed on the Nasdaq Small Cap market and the Boston Stock Exchange under the symbols "DCTHW" and "DCT/U," respectively. The redeemable common stock purchase warrants we issued in 2003

are listed on the Boston Stock Exchange under the symbol "DCT&W."

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

	2003	
	High	Low
Quarter ended March 31, 2003	$1.79	$0.94
Quarter ended June 30, 2003	2.35	0.56
Quarter ended September 30, 2003	1.55	1.00
Quarter ended December 31, 2003	1.39	0.86

	2002	
	High	Low
Quarter ended March 31, 2002	$2.90	$0.94
Quarter ended June 30, 2002	1.90	0.68
Quarter ended September 30, 2002	1.11	0.63
Quarter ended December 31, 2002	2.66	0.31

As of February 28, 2004, there were approximately 81 stockholders of record of our Common Stock and approximately 686 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, 2003 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	Weighted average exercise price of outstanding options, warrants and rights	Num rem for und com (ex ref

	(a)	(b)	(a)
Equity compensation plans approved by security holders	1,520,678	$2.09	
Equity compensation plans not approved by security holders	--	--	
Total	1,520,678	$2.09	

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(1) As of December 31, 2003, options to purchase 1,520,678 shares of the Company's common stock were outstanding which exceeded by 44,541 the aggregate number of shares reserved for the Company's option plans. As a result of options which expired or were forfeited in January 2004, the remaining options outstanding were within the limits of the option plans.

During the fourth quarter of 2003, no purchases were made by or on behalf of us or any "affiliated purchaser," as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, of any shares of our Common Stock.

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. Enrolled patients will continue to be followed.

NCI is currently preparing a clinical trial protocol for a Phase II trial of melphalan, based on the data collected in the Phase I study. Enrollment in this Phase II study is expected to begin during 2004. The Principal Investigator at the

NCI has informed the Company that he has presented his findings in appropriate medical forums and is reviewing his data in preparation for a meeting with the FDA to discuss the Phase II protocol..

We also announced that the Therapeutics Goods Adminstration, Australia's equivalent of the U.S. FDA, has given the Company approval to commence a Phase III trial at the Sydney Melanoma Unit to proceed with study of the Delcath drug delivery system for inoperable cancer in the liver. We are currently identifying and recruiting patients and are in discussions with other sites worldwide.

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 doxorubicin with the Delcath system and Phase I and 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

Our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures at least through 2004. 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 it 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 in 2005. 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. Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's financial statements included herein. The Company has not adopted any significant new accounting policies during the twelve months ended December 31, 2003.

(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-17

Independent Auditors' Report

Balance Sheet as of December 31, 2003

Statements of Operations for the years ended December 31, 2003 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2003

Statements of Stockholders' Equity for the years ended December 31, 2003 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2003

Statements of Cash Flows for the years ended December 31, 2003 and 2002 and cumulative from inception (August 5, 1988) to December 31, 2003

Notes to Financial Statements

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

Information in response to Item 304 of Regulation S-B is not included herein because such information has been "previously reported," as defined in Rule 12b-2 under the Exchange Act.

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.

The information required by Item 307 of Regulation S-B as amended effective August 14, 2003 will be included in our annual report for our first fiscal year ending on or after April 15, 2005.

The information required by Item 308 of Regulation S-B as amended effective August 14, 2003 will be included in our annual report for our first fiscal year

ending on or after April 15, 2005

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 2004 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 is incorporated into this form 10-KSB by reference to the Definitive Proxy Statement.

Item 13. Exhibits and Reports on Form 8-K.

(a) Exhibits

3.1 Amended and Restated Certificate of Incorporation of Delcath Systems, Inc., as amended. [(incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 (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

Exhibit No. Description

Registration Statement on Form SB-2 (Registration No. 333-39470)).

4.1 Warrant Agreement, dated January as of 5, 2001, by and between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form

10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).

4.2 Warrant No. W-2 to purchase up to 150,000 units granted to Euroland Marketing Services, Ltd. (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).

4.3 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)).

4.4 Form of Warrant Agreement by and between Delcath Systems, Inc. and Whale Securities Co., L.P. (incorporated by reference to Exhibit 4.2 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

4.5 Form of Warrant Agent Agreement by and among Delcath Systems, Inc., Whale Securities Co., L.P., and American Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.3 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

4.6 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)).

4.7 Specimen 2003 Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).

4.8 Form of Warrant Agent Agreement by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as warrant agent, with respect to the 2003 Warrants (incorporated by reference to Exhibit 4.8 to Amendment No. 3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).

4.9 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).

10.1 1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

10.2 1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

10.3 2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to 10.3 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 Employment Agreement, effective as of October 1, 2003, by and among

Delcath Systems, Inc. and M. S. Koly.

Exhibit No.	Description
10.6	Employment Agreement, effective as of October 1, 2003, by and among Delcath Systems, Inc. and Samuel Herschkowitz.
10.7	Exclusive Distributorship Agreement, dated as of December 27, 1996, by and between Nissho Corporation and Delcath Systems, Inc. (incorporated by reference to Exhibit 10.6 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
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).
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).
14	Code of Business Conduct.
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.

(b) Reports on Form 8-K

During the last quarter of the year covered by this report, we did not file any Reports on Form 8-K.

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 30, 2004

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 30, 2004
/s/ Paul M. Feinstein Paul M. Feinstein	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2004
/s/ Samuel Herschkowitz, M.D. Samuel Herschkowitz, M.D.	Chairman of the Board	March 30, 2004
/s/ Mark A. Corigliano Mark A. Corigliano	Director	March 30, 2004
/s/ Daniel Isdaner Daniel Isdaner	Director	March 30, 2004
/s/ Victor Nevins Victor Nevins	Director	March 30, 2004

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

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Independent Auditors' Report

The Board of Directors
Delcath Systems, Inc.:

We have audited the accompanying balance sheet of Delcath Systems, Inc. (a development stage company) as of December 31, 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2003 and for the period from August 5, 1988 (inception) to December 31, 2003. 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 auditing standards generally accepted

in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 enumerated above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage company) as of December 31, 2003, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2003 and for the period from August 5, 1988 (inception) to December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

Eisner LLP

New York, NY
February 11, 2004
With respect to Note 6,
March 22, 2004

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Balance Sheet

	December 31, 2003
Assets	
Current assets:	
Cash and cash equivalents	$ 313,615
Certificates of deposit	2,017,321
Interest receivable	14,272
Prepaid insurance	47,500
Total current assets	2,392,708
Furniture and fixtures, net	13,787
Due from affiliate	24,000
Total assets	$ 2,430,495
Liabilities and Stockholders' Equity	

Current liabilities:	
Accounts payable and accrued expenses	$ 260,200
Total current liabilities	260,200
Stockholders' equity:	
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	--
Common stock, $.01 par value; 35,000,000 shares authorized; 9,772,732 shares issued and 9,744,632 outstanding	97,446
Additional paid-in capital	21,777,065
Deficit accumulated during development stage	(19,704,216)
Total stockholders' equity	2,170,295
Total liabilities and stockholders' equity	$ 2,430,495

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Statements of Operations

	Year ended December 31, 2003	Year ended December 31, 2002	Cumulative from inception (August 5, 1988) to December 31, 2003
Costs and expenses:			
General and administrative	$ 707,737	$ 723,763	$ 6,011,046
Research and development	1,598,615	1,173,275	13,009,496
Total costs and expenses	2,306,352	1,897,038	19,020,542

Operating loss	(2,306,352)	(1,897,038)	(19,020,542)
Other income (expense):			
Interest income	55,941	89,992	986,404
Interest expense	--	--	(171,473)
Net loss	$ (2,250,411)	$ (1,807,046)	$ (18,205,611)
Common share data:			
Basic and diluted loss per share	$ (0.30)	$ (0.44)	
Weighted average number of basic and diluted common shares outstanding	7,453,349	4,085,049	

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Statements of Stockholders' Equity

Years ended December 31, 2003 and 2002 and
cumulative from inception (August 5, 1988) to December 31, 2003

	Common stock $.01 par			
	Issued		In treasury	
	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	--	$ --
Sale of preferred stock, August 22, 1988	--	--	--	--
Shares returned as of March 8, 1990	--	--	(414,059)	(4,141)
Sale of stock, October 2, 1990	--	--	17,252	173
Sale of stock, January 23, 1991	--	--	46,522	465
Sale of stock, August 30, 1991	--	--	1,353	14
Sale of stock, December 31, 1992	--	--	103,515	1,035

Sale of stock, July 15, 1994	--	--	103,239	1,032
Sale of stock, December 19, 1996	--	--	39,512	395
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984
Sale of stock, December 31, 1997	53,483	535	--	--
Exercise of stock options	13,802	138	3,450	35
Shares issued as compensation	2,345	23	828	8
Amortization of compensatory stock options granted	--	--	--	--
Forfeiture of stock options	--	--	--	--
Shares issued in connection with exercise of warrants	21,568	216	--	--
Sale of stock, January 16, 1998	34,505	345	--	--
Sale of stock, September 24, 1998	3,450	35	--	--
Shares returned, April 17, 1998	(3,450)	(35)	--	--
Amortization of compensatory stock options granted	--	--	--	--
Forfeiture of stock options	--	--	--	--
Exercise of stock options	8,626	86	--	--
Sale of stock, June 30, 1999	46,987	470	--	--
Amortization of compensatory stock options granted	--	--	--	--
Forfeiture of stock options	--	--	--	--
Shares issued in connection with exercise of warrants	2,300	23	--	--
Sale of stock, April 14, 2000	230,873	2,309	--	--
Dividends paid on preferred stock	690,910	6,909	--	--
Conversion of preferred stock	833,873	8,339	--	--
Sale of stock, October 19, 2000	1,200,000	12,000	--	--
Shares issued as compensation for stock sale	85,000	850	--	--
Stock options issued as compensation	--	--	--	--
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	--	--
Stock warrants issued as compensation	--	--	--	--
Deficit accumulated from inception to December 31, 2001	--	--	--	--
Balance at December 31, 2001	3,903,816	39,038	--	--
Sale of stock on April 3, 2002	243,181	2,432	--	--
Repurchases of stock, November and December 2002			(28,100)	(281)
Net loss for year ended December 31, 2002	--	--	--	--
Balance at December 31, 2002	4,146,997	$ 41,470	(28,100)	$ (281)
Sale of stock May 20, 2003 including underwriter's exercise of overallotment option	3,895,155	38,952	--	--
Proceeds from sale of unit option	--	--	--	--
Exercise of 2003 Warrants	1,730,580	17,305	0	0
Net loss for year ended December 31, 2003				

Balance at December 31, 2003	9,772,732	97,727	(28,100)	(281)

	Preferred Stock		Class A preferred stock		Cl prefer
	$.01 par value		$.01 par value		$.01
	No. of shares	Amount	No. of shares	Amount	No. of shares
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 as of March 8, 1990	--	--	--	--	--
Sale of stock, October 2, 1990	--	--	--	--	--
Sale of stock, January 23, 1991	--	--	--	--	416,675
Sale of stock, August 30, 1991	--	--	--	--	--
Sale of stock, December 31, 1992	--	--	--	--	--
Sale of stock, July 15, 1994	--	--	--	--	--
Sale of stock, December 19, 1996	--	--	--	--	--
Shares issued 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	--	--	--	--	--
Amortization of compensatory stock options granted	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--
Shares issued in connection with exercise of warrants	--	--	--	--	--
Sale of stock, January 16, 1998	--	--	--	--	--
Sale of stock, September 24, 1998	--	--	--	--	--
Shares returned, April 17, 1998	--	--	--	--	--
Amortization of compensatory stock options granted	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--
Exercise of stock options	--	--	--	--	--
Sale of stock, June 30, 1999	--	--	--	--	--
Amortization of compensatory stock options granted	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--
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
Sale of stock, October 19, 2000	--	--	--	--	--
Shares issued as compensation					

for stock sale	--	--	--	--	--
Stock options issued as compensation	--	--	--	--	--
Sum of fractional common shares cancelled after year 2000 stock splits	--	--	--	--	--
Stock warrants issued as compensation	--	--	--	--	--
Deficit accumulated from inception to December 31, 2001	--	--	--	--	--
Balance at December 31, 2001	--	--	--	--	--
Sale of stock on April 3, 2002	--	--	--	--	--
Repurchases of stock, November and December 2002	--	--	--	--	--
Net loss for year ended December 31, 2002	--	--	--	--	--
Balance at December 31, 2002	0	$ 0	0	$ 0	
Sale of stock May 20, 2003 including underwriter's exercise of overallotment option	--	--	--	--	--
Proceeds from sale of unit option	--	--	--	--	--
Exercise of 2003 Warrants	0	0	0	0	
Net loss for year ended December 31, 2003					
Balance at December 31, 2003	0	$ 0	0	$ 0	

	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 as of March 8, 1990	4,141	--	--
Sale of stock, October 2, 1990	24,827	--	25,000
Sale of stock, 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, July 15, 1994	1,120,968	--	1,122,000
Sale of stock, December 19, 1996	999,605	--	1,000,000
Shares issued 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	34,454	--	34,485
Amortization of compensatory stock options granted	2,496,347	--	2,946,347
Forfeiture of stock options	(279,220)	--	(279,220)
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, April 17, 1998	(4,965)	--	(5,000)
Amortization of compensatory stock options granted	1,166,418	--	1,666,418
Forfeiture of stock options	(407,189)	--	(407,189)
Exercise of stock options	67,414	--	67,500
Sale of stock, June 30, 1999	775,722	--	776,192
Amortization of compensatory stock options granted	98,186	--	98,186
Forfeiture of stock options	(554,371)	--	(554,371)
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, October 19, 2000	5,359,468	--	5,371,468
Shares issued as compensation for stock sale	(850)	--	--
Stock options issued as compensation	3,800	--	3,800
Sum of fractional common shares cancelled after year 2000 stock splits	1	--	--
Stock warrants issued as compensation	198,000	--	198,000
Deficit accumulated from inception to December 31, 2001	--	(14,148,154)	(14,148,154)
Balance at December 31, 2001	18,835,160	(15,646,759)	3,227,439
Sale of stock on April 3, 2002	265,068	--	267,500
Repurchases of stock, November and December 2002	(50,822)	--	(51,103)
Net loss for year ended December 31, 2002	--	(1,807,046)	(1,807,046)
Balance at December 31, 2002	$19,049,406	$(17,453,805)	$ 1,636,790
Sale of stock May 20, 2003 including underwriter'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	0	1,291,200
Net loss for year ended December 31, 2003		(2,250,411)	(2,250,411)
Balance at December 31, 2003	$21,777,605	(19,704,216)	2,170,295

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31,	
	2003	2
Cash flows from operating activities:		
Net loss	$ (2,250,411)	$ (1,80
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	--	
Stock and warrant compensation expense issued for consulting services	--	
Depreciation expense	4,990	6
Amortization of organization costs	--	
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses	49,083	(2
(Increase) decrease in interest receivable	(8,865)	47
Due from affiliate	--	
Increase (decrease) in accounts payable and accrued expenses	85,030	
Net cash used in operating activities	(2,120,173)	(1,78
Cash flows from investing activities:		
Purchase of furniture and fixtures	(5,029)	(
Purchase of short-term investments	(2,017,321)	(37
Proceeds from maturities of short-term investments	370,000	1,500
Organization costs	--	
Net cash (used in) provided by operatin activities	(1,652,350)	1,123
Cash flows from financing activities:		
Costs in connection with sale of stock and exercise of warrants	238,571	(23
Net proceeds from sale of stock and exercise of stock options and warrants	2,783,916	267
Repurchases of outstanding common stock	--	(5

Dividends paid	--	
Proceeds from short-term borrowings	--	
Net cash provided by (used in) financin activities	3,022,487	(2
(Decrease) increase in cash and cash equivalents	(750,035)	(67
Cash and cash equivalents at beginning of period	1,063,650	1,743
Cash and cash equivalents at end of period	$ 313,615	$ 1,063
Cash paid for interest	$ --	$
Supplemental non-cash activities:		
Conversion of debt to common stock	$ --	$
Common stock issued for preferred stock dividends	$ --	$
Conversion of preferred stock to common stock	$ --	$
Common stock issued as compensation for stock sale	$ --	$

See accompanying notes to financial statements.

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

December 31, 2003 and 2002

(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-marketing 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. The preparation of financial statements in conformity with such accounting principles 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) Furniture and Fixtures

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 amounted to $26,066 at December 31, 2003.

(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 expense is recorded on the date of grant only if the current fair market value of the

underlying stock exceeds 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.

In 1996, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation," 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, 2003 and 2002 would have been increased to the pro forma amounts indicated as follows:

	2003	2002
Net loss	$ (2,250,411)	$ (1,807,046)
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	(82,568)	(44,769)
Pro forma net loss	(2,332,979)	(1,851,815)
Loss per share (basic and diluted):		
As reported	$ (0.30)	$ (0.44)

December 31, 2003 and 2002

Pro forma	(0.31)	(0.45)

The per share weighted average fair value of stock options granted during 2003 and 2002 was $.32 and $.28, respectively, estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for the grants for 2003 and 2002, respectively: risk free interest rates of 3.49% and 2.84%, and volatility of 29% and 41%, while no dividend yield and expected lives of five years were assumed for both years.

(f) Loss Per Share

The Company follows the provisions of SFAS No. 128, "Earnings Per Share", which requires presentation of both basic and diluted earnings per share (EPS) on the face of the Statements of Operations. Basic EPS excludes dilution, and is computed using the weighted average number of common shares outstanding during the period. The diluted EPS calculation assumes all dilutive stock options or contracts to issue Common Stock were exercised or converted into Common Stock at the beginning of the period.

For the years ended December 31, 2003 and 2002, the following potential common shares were excluded from the computation of diluted EPS because their effects would be antidilutive:

	2003	2002
Shares issuable upon exercise of options	1,520,678	1,145,684
Shares issuable upon exercise of warrants	4,628,970	1,786,985
Totals	6,149,648	2,932,669

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 computation.

(g) 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.

(h) Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers highly liquid debt instruments with maturities of three months or less at date of acquisition to be cash equivalents. At December 31, 2003 cash equivalents excluded certificates of deposit in the amount of $2,017,321.

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

December 31, 2003 and 2002

(i) Stock Splits

All share and per share amounts give retroactive effect to stock splits effected by the Company.

(2) Stockholders' Equity

(a) Stock Issuances

BGH Medical Products, Inc. (name later changed to Delcath Systems, Inc.), a Delaware corporation (BGH - Delaware), was formed on August 5, 1988. As of August 22, 1988, BGH Medical Products, Inc., a Connecticut corporation (BGH - Conn.), was merged into BGH -Delaware, the surviving corporation. As of the merger date, the authorized capital stock of BGH - Conn. consisted of 5,000 shares of common stock, par value $.01 per share, of which 1,000 shares were issued and outstanding. Upon the merger, each BGH - Conn. Common Share outstanding was converted into 621.089 BGH - Delaware Common Shares. As a result of the conversion, BGH - Delaware issued 621,089 shares of Common Stock at $.01 par value. The aggregate amount of the par value of all Common Shares issued as a result of the exchange, $6,211, was credited as the Common Stock capital of BGH - Delaware, and the difference in respect of the capital account deficiency was charged to additional paid-in capital.

On August 22, 1988, BGH - Delaware then sold in a private placement 2,000,000 shares of Class A Preferred Stock, with a par value of $.01, to two affiliated venture capital funds for an aggregate amount of $500,000 in cash.

On March 8, 1990, 414,059 shares of Common Stock were returned to the Company by certain stockholders as treasury stock due to relevant technology milestones not being fully achieved within the specified time period, in accordance with provisions of a stockholders' agreement.

On October 2, 1990, the Company sold 17,252 shares of Common Treasury Stock, $.01 par value, for an aggregate amount of $25,000.

On January 23, 1991, the Company offered in a private placement shares of Common Stock and/or Class B Preferred Stock at $7.39 and $2.55 per share respectively for an aggregate maximum amount of $2,000,000. Under the terms of the private placement, 46,522 shares of Common Treasury Stock and 416,675 shares of Class B Preferred Stock were sold, yielding net proceeds to the Company of $1,406,322. The Common Stock and Class B Preferred Stock sold each has a par value of $.01, resulting in an increase in additional paid-in capital of $1,401,690 The two affiliated venture capital funds that owned the Class A Preferred Shares purchased 117,650 of the Class B Preferred Shares

sold in the private placement.

On August 30, 1991, the Company sold an additional 1,353 shares of Common Treasury Stock at $7.39 per share, yielding proceeds to the Company of $10,001. The shares have a par value of $.01, resulting in an additional paid-in capital amount of $9,987.

In a December 1992 private placement, the Company sold 103,515 shares of Common Stock held in its treasury at $10.14 per share for a total placement of $1,050,000 ($1,015,004 after expenses). The shares issued have a par value of $.01, resulting in an additional paid-in capital amount of $1,048,965 ($1,013,969 after expenses). The two affiliated venture capital funds that owned the Class A Preferred Shares purchased 27,604 of the Common Treasury Shares sold.

Effective January 1, 1994, the Company issued 1,725 shares of Common Treasury Stock at $1.45 per share for a total price of $2,500 upon the exercise of stock options by an employee of the Company.

During the first quarter of 1994, the Company increased its authorized number of Common Shares from 5,000,000 to 15,000,000.

On July 15, 1994, the Company sold through a private placement offering, units at a price of $51,000 per unit. Each unit consisted of 4,693 Common Shares and 469 Warrants, each of which entitled the holder to purchase one share of Common Stock for $10.87. In connection therewith, the Company sold twenty-two (22) units (103,239 Common Shares and 10,324 Warrants expiring August 30, 1997) for total proceeds of $1,122,000. The two affiliated venture capital funds that owned the Class A Preferred Shares purchased six (6) of the units sold. During August 1997, the holders of Warrants exercised 8,916 Warrants to purchase 8,916 Common Shares at $10.87 each for total proceeds of $96,900. The remaining Warrants expired unexercised.

Effective January 1, 1995, the Company issued 1,725 shares of Common Treasury Stock at $1.45 per share for a total price of $2,500 upon the exercise of stock options by an employee of the Company.

Effective January 1, 1996, the Company issued 828 shares of Common Stock, valued at $10.87 per share for a total of $9,000, as compensation for consulting services.

On December 19, 1996, the Company sold through a private transaction 39,512 shares of Common Stock for total proceeds of $1,000,000. In connection with the offering, the purchaser obtained sole distribution rights for the Company's products in Japan, Korea, China, Taiwan, and Hong Kong through December 31, 2004. No value was attributed to the distribution rights. In addition, under certain conditions, the purchaser will be required to buy certain products from the Company.

On April 26, 1996, the Company entered into short-term borrowing agreements with 26 investors under which it borrowed $1,704,964 bearing interest at 10.25% per annum. Under the terms of the agreements, on December 22, 1996, the short-term borrowings were converted into 156,879 shares of Common Stock, based on a conversion price of $10.87 per share, and 78,438 Warrants, expiring April 25, 1999, entitling the holders to purchase 78,438 additional shares of Common Stock at $10.87 per share. The two affiliated venture capital funds discussed above provided

$250,000 of the short-term loan, converting that debt into approximately 23,003 shares of Common Stock and 11,502 Warrants. From April 26, 1996 through December 22, 1996, interest of $114,948 accrued on the borrowings. Such interest was paid in January 1997. During September 1997, the holders of Warrants exercised 1,150 Warrants to purchase 1,150 Common Shares at $10.87 each for total proceeds of $12,499. During December 1997, the two affiliated venture capital funds exercised their 11,502 Warrants to purchase 11,502 Common Shares at $10.87 each for total proceeds of $124,999. During April 1999, the holders of Warrants exercised 2,300 Warrants to purchase 2,300 Common Shares at $10.87 each for total proceeds of $24,998. The remaining Warrants expired unexercised.

In 1997, the Company issued 2,345 shares of Common Stock, valued at $10.87 per share based on a 1996 agreement, for a total cost of $25,485, as compensation for consulting services.

From September 1997 through December 31, 1997, the Company received $775,000 and issued 53,483 shares of Common Stock. During January 1998, the Company received an additional $500,000 and issued another 34,505 shares of Common Stock. In April 1998, under the terms of restricted stock sale agreements, the Company issued to the purchasers of the 87,988 shares of Common Stock 11,732 three-year Warrants entitling the holders to purchase 11,732 Common Shares at $10.87 per share. These Warrants expired unexercised in April 2001.

In December 1997, the holder of non-incentive stock options exercised 13,802 options to purchase 13,802 restricted Common Shares at $1.88 each for total proceeds of $26,000.

In April 1998, a venture capital firm exercised 8,626 non-incentive stock options to purchase 8,626 restricted Common Shares at $7.83 each for total proceeds of $67,500.

In April 1998, in connection with the settlement of a dispute with a former director, the Company cancelled 3,450 shares of Common Stock previously held by the former director in return for $1.45 per share,

the price originally paid by the former director.

In September 1998, the Company sold 3,450 shares of restricted Common Stock to an individual for $16.52 per share, yielding proceeds to the Company of $57,000.

In June 1999, the Company sold 46,987 shares of Common Stock to individual investors for $16.52 per share and Warrants entitling the holders to purchase 5,218 Common Shares at $14.87 per share (which warrants expired on April 30, 2002), yielding proceeds to the Company of $776,192.

In April 2000, the Company sold 230,873 Common Shares at $2.17 per share to existing stockholders in a rights offering yielding proceeds to the Company of $501,825.

The Company completed an initial public offering ("IPO") on October 19, 2000 of 1,200,000 units for $6.00 per unit, each unit consisting of one share of Common Stock and one redeemable Warrant to purchase one share of Common Stock at a price of $6.60 until October 18, 2005. In connection with the initial public offering, the Company received $7,200,000 before offering costs ($5,371,468 after expenses). The Company also issued to the underwriter Warrants to

purchase 120,000 units for $6.60 per unit, each unit consisting of one Common Share and one redeemable Warrant to purchase one share of Common Stock at a price of $10.50 until October 18, 2005. The Company also issued 85,000 shares of Common Stock valued at $510,000 for legal services provided in connection with the offering.

Also, in connection with the initial public offering, the holders of the 2,000,000 outstanding shares of the Company's Class A Preferred Stock and the 416,675 outstanding shares of the Company's Class B Preferred Stock agreed to convert their shares into Common Stock prior to the closing of the offering. Upon the conversion of the Company's Class A Preferred Stock and the Company's Class B Preferred Stock into 833,873 shares of Common Stock, the holders of the Class A and Class B shares received an aggregate of $499,535 in cash and 690,910 shares of Common Stock valued at $999,070 in payment of declared dividends.

In December 2000, the Company issued 1,720 Common Stock options at an exercise price of $3.31, fair valued at $2.21 per option for a total of $3,800, and 1,720 Warrants to purchase Common Stock at an exercise price of $6.00, fair valued at $0 per Warrant, as compensation for consulting services. Both the options and Warrants expire December 1, 2005.

The Company issued the following common stock warrants in 2001 for

consulting services:

(1) 150,000 fully vested warrants to purchase 150,000 units at $7.00 per unit, through January 4, 2005, each unit consisting of one fully-paid and non-assessable share of common stock, and one Common Stock Purchase Warrant entitling the holder to purchase one share of Common Stock for $6.60 per share. None of these warrants has been exercised as of December 31, 2003. Such warrants, valued at $175,000, were recognized as an expense in the first quarter of 2001.

(2) 150,000 warrants to purchase up to 150,000 shares of Common Stock, through April 30, 2005, for $6.60 per share. 25,000 of such warrants vested in 2001 and the remaining 125,000 warrants would have vested if the share price of the Company's Common Stock exceeded certain share price levels above the IPO price by May 2002. As of May 2002, none of the thresholds had been met, and the 125,000 remaining warrants did not vest and were forfeited. None of the 25,000 vested warrants had been exercised as of December 31, 2003. The 25,000 vested, non-contingent warrants have been valued at $23,000, and were recognized as an expense in the first quarter of 2001. The expenses, as noted in (1) and (2) above, recognized with these two warrant issues are non-cash expenses.

The values of the above warrants were $1.17 per warrant for warrants described in (1) above, and $ .90 per warrant for the 25,000 warrants that vested immediately described in (2) above, and were estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions, respectively: risk free interest rates of 4.95% and 5.9%, volatility of 26.7% and 22.9%, expected lives of four years and four and one half years, with no dividend yield for either issue.

In 2001, the Company cancelled a total of 36 shares of Common Stock which represented the total of fractional shares resulting from stock splits during September and October 2000 in connection with the Company's initial public offering.

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.

On April 3, 2002, the Company received $267,500 by completing a private placement of 243,181 shares of its Common Stock and warrants to purchase up to 20,265 shares of Common Stock at an exercise price of $1.32 per share that expire on April 3, 2005.

On January 31, 2003, the stockholders approved an amendment to the Company's certificate of incorporation to increase the authorized number of shares of Common Stock from 15 million to 35 million.

On May 20, 2003, the Company completed the sale of 677,419 units of its securities at a selling price of $3.10 per unit. Each unit consisted of five shares of common stock and five warrants (the "2003 Warrants") each to purchase one share of common stock. The 2003 Warrants are exercisable at $0.775, and they expire on May 20, 2008. A total of 3,387,095 shares of common stock and 2003 Warrants each were issued, and the Company received gross proceeds of $2,099,999. In addition, the Company granted the underwriters an option to purchase at $0.62 per share up to an aggregate of an additional 15% of the total units sold in the public offering. On June 10, 2003 the underwriters exercised their option for the full allotment of additional units, and the Company issued 508,060 shares of its common stock and 2003 Warrants each, and received gross proceeds of $314,997. The Company received $68 for granting the underwriters an option to purchase until May 14, 2008, 67,741 units at 165% of the offering price. As a result of the foregoing, the Company received $2,415,064 of proceeds ($1,492,716) after underwriting fees and other expenses).

As of December 31, 2003, the Company has received $1,291,200 of net proceeds from the exercise of 2003 Warrants for which it has issued 1,730,580 shares of its common stock. The new warrants trade under the symbol "DCTHZ.

Costs of $238,571 incurred through December 31, 2002 in connection with the May 2003 sale of units, which had been deferred at December

31, 2002, were charged to additional paid-in capital upon completion of the sale in 2003.

(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 and the 2001 Stock Option Plan (collectively, the "Plans") under which stock options may be granted. Additionally, the Company has entered into separate contracts apart from the Plans under which options to purchase Common Stock have been granted. 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 and 2001, respectively, the 2000 and 2001 Stock Option Plans 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 the period January 1, 2002 through December 31, 2003 is as follows:

	The Plans		Other Option Grants	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2001	885,678	$2.94	17,252	$2.90
Granted during 2002	260,000	.71	--	--
Expired during 2002	--		(17,252)	2.90
Outstanding at December 31, 2002	1,145,678	2.43	--	--
Granted during 2003	475,000	1.03	--	--
Forfeited during 2003	(86,500)	.96	--	--

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

December 31, 2003 and 2002

Expired during 2003	(13,500)	1.23		
Outstanding at December 31, 2003	1,520,678	$2.09	--	$ --

The following summarizes information about shares subject to option at December 31, 2003:

Options outstanding				Options
Number outstanding	Range of exercise prices	Weighted average exercise price	Weighted average remaining life in years	Number exercisable
100,000	$ .60		3.92	100,000
220,000	.71		4.25	110,000
120,000	.85		4.00	120,000
475,000	1.03		4.67	0
172,525	2.90		2.00	172,525
164,020	3.31		2.95	164,020
269,133	4.93		1.00	269,133
1,520,678	$ .60 - $4.93	$2.09	2.92	935,678

As of December 31, 2003, options to purchase 1,520,678 shares of the Company's common stock were outstanding which exceeded by 44,541 the aggregate number of shares reserved for the Company's option plans. As a result of options which expired or were forfeited in January 2004, the remaining options outstanding were within the limits of the option plans.

At December 31, 2002, options for 729,184 shares were exercisable at a weighted average exercise price of $3.38 per share.

(3) Income Taxes

As of December 31, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately $14,908,000. A portion of that amount, $13,611,000, 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 $1,297,000 is available to offset future federal taxable income, if any, through 2023. The available net operating loss carryforwards after applying the annual limitation under Section 382 resulted in a deferred tax asset of approximately $1,280,000 at December 31, 2003 ($4,380,000 at December 31, 2002). 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, 2003 and 2002. The valuation allowance decreased $3,100,000 during the year ended December 31, 2003, and increased $603,000 during the year ended December 31, 2002.

(4) Due From Affiliate

The Company sublet office space from a corporation controlled by an officer of the Company (the "affiliate"), whose lease with the landlord expired in August 1997. Thereafter, the Company's occupancy of the premises continued pursuant to an informal arrangement, under which the Company remitted monthly rental payments directly to the landlord. The informal arrangement was replaced as of January 1, 2002 with a lease agreement between the Company and the landlord (see Note 5). In connection with its occupancy, the Company paid the affiliate $24,000 which the affiliate then paid to the landlord as a deposit on the lease.

(5) Rents

On April 1, 2002, the Company executed an Amendment of Lease (the "Amendment") directly with the landlord. The Amendment was effective January 1, 2002 and expired December 22, 2003. Rent expense under this lease for the year ended December 31, 2003 and 2002 was $87,376 and $89,082, respectively. The Company currently occupies space on a month-to-month basis.

(6) Subsequent Event - Sale of Common Stock and Warrants

On March 22, 2004, the Company completed the sale of approximately 1,200,000 shares of its Common Stock and the issuance of warrants to

purchase approximately 300,000 common shares at $3.01 per share in a private placement to institutional and accredited investors. The Company received net proceeds (before future registration costs) of approximately $2,700,000 in this transaction, and has agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securities Act of 1933.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Delcath Systems, Inc., as amended. [(incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 (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	Warrant Agreement, dated January as of 5, 2001, by and between Delcath Systems, Inc. and Euroland Marketing Solutions, Ltd. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
4.2	Warrant No. W-2 to purchase up to 150,000 units granted to Euroland Marketing Services, Ltd. (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 2000 (Commission File No. 001-16133)).
4.3	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)).
4.4	Form of Warrant Agreement by and between Delcath Systems, Inc. and Whale Securities Co., L.P. (incorporated by reference to Exhibit 4.2 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.5	Form of Warrant Agent Agreement by and among Delcath Systems, Inc., Whale Securities Co., L.P., and American Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.3 to Amendment No. 5 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.6	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)).
4.7	Specimen 2003 Warrant (incorporated by reference to Exhibit 4.2 to

Amendment No. 1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).

4.8 Form of Warrant Agent Agreement by and between Delcath Systems, Inc. and American Stock Transfer & Trust Company, as warrant agent, with respect to the 2003 Warrants (incorporated by reference to Exhibit 4.8 to Amendment No. 3 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-101661)).

4.9 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).

10.1 1992 Incentive Stock Option Plan (incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

10.2 1992 Non-Incentive Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

10.3 2000 Stock Option Plan (incorporated by reference to Exhibit 10.3 to 10.3 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 Employment Agreement, effective as of October 1, 2003, by and among Delcath Systems, Inc. and M. S. Koly.

10.6 Employment Agreement, effective as of October 1, 2003, by and among Delcath Systems, Inc. and Samuel Herschkowitz.

10.7 Exclusive Distributorship Agreement, dated as of December 27, 1996, by and between Nissho Corporation and Delcath Systems, Inc. (incorporated

by reference to Exhibit 10.6 to Registrant's Registration Statement on Form SB-2 (Registration No. 333-39470)).

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).

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).

14 Code of Business Conduct.

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.