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, 2001

[_] 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 Warrants	Boston Stock Exchange

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

Common Stock, par value $0.01 per share
Redeemable 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 $1.39 per share, was $ 3,331,435 as of February 21, 2002.
At February 21, 2002, the registrant had outstanding 3,903,816 shares of par value $0.01 Common Stock.

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

GENERAL

Delcath Systems, Inc. ("Delcath" or the "Company") was originally formed by a team of physicians on August 5, 1988 as BGH Medical Products, Inc., a Delaware corporation. On August 22, 1988, BGH Medical Products Inc., a Connecticut corporation, was merged into it. On May 7, 1990, the surviving Delaware corporation changed its name to Delcath Systems, Inc.

Delcath has developed a system, the Delcath system, to isolate the liver from the general circulatory system and to administer chemotherapy and other therapeutic agents directly to the liver.

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 for the system in the United States and possibly in foreign markets.

STRATEGY

Our objective is 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:

- Complete 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. FDA pre-marketing approval of our application will permit us to market the Delcath system to administer doxorubicin in the treatment of melanoma that has spread to the liver.

- Obtain 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 using melphalan, a chemotherapeutic agent. See "Our Clinical Trials and Agreement with National Cancer Institute." In addition to researching the use of other chemotherapeutic 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 or raise additional funds for these purposes. 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 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. We intend to seek to enter into arrangements with strategic partners who have experience with obtaining regulatory approval and marketing medical devices in those markets and are willing to bear the cost of those activities.

THE CANCER TREATMENT MARKET

The American Cancer Society projects that about 1,285,000 Americans will be diagnosed with cancer in 2002. According to the American Cancer Society's "Cancer Facts and Figures 2002", cancer remains the second leading

cause of death in the United States. 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 2002," estimates the overall costs of cancer, in the year 2001, to be $157 billion, including $56 billion in direct medical costs, $16 billion for indirect morbidity costs attributable to lost productivity due to illness, and $85 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. Secondary, or metastatic, 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. In the liver, tumors can be surgically removed only when they are located in one of the liver's two lobes. According to a January 3, 2000 article on liver cancer in the HOUSTON CHRONICLE, an estimated 75% 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 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 a 1999 article in the WASHINGTON POST, liver cancer is the third most common form of cancer worldwide. The worldwide incidence of liver cancer is estimated to be in excess of 1,500,000 new patients each year, and there are an estimated 1,250,000 deaths worldwide caused by all forms of liver cancer. According to a 1999 article in the NEW ENGLAND JOURNAL OF MEDICINE, researchers reported that annual new diagnoses of liver cancer increased from 1.4 cases per 100,000 persons in the late 1970s to 2.4 cases per 100,000 persons in the 1990s. The American Cancer Society has projected that in the United States there will be approximately 16,600 new cases of primary liver cancer and 53,600 new cases of malignant melanoma in 2002.

Liver cancer is among the most virulent forms of cancer. In the United States, five-year survival rates are usually not more than 5%, according to the National Cancer Institute.

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.

LIVER CANCER TREATMENTS

The prognosis for primary and secondary liver cancers 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 include surgery, chemotherapy, cryosurgery, percutaneous ethanol injection and radiation.

SURGERY

While surgery is considered the "gold standard" treatment option to address liver tumors, an estimated 75% of liver cancer patients 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 heath 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 resection 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 1980s, 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 excessive 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 tract 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 cancer treatments.

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, tumor ablation 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.

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 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 such protection from the side-effects of chemotherapy that is provided by the Delcath system to other parts of the body allows for higher chemotherapy doses to be administered 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:

- 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 procedure 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. 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 exits 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 and the heart, thus restoring the cleansed blood to normal circulation. Infusion is administered over a period of 30 minutes. Filtration occurs during infusion and for 30 minutes afterward. The catheters are removed and manual pressure is maintained on the catheter puncture sites for approximately 15 minutes. The entire procedure takes approximately two to three hours to administer.

During Phase I and 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 the Robert Wood Johnson Medical School/Cancer Institute of New Jersey.

OUR PHASE III CLINICAL TRIALS

Phase III human clinical trials are a prerequisite for FDA pre-marketing 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 have conducted Phase I and II human 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 23 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.

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, 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-market 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 and 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. 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.

With a substantial portion of the proceeds that we received from our initial public offering, we intend to conduct Phase III human clinical trials designed to demonstrate 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.

In December 1999, the FDA approved the protocols for conducting the Phase III clinical trials.

We expect the Phase III clinical trials to be conducted at several medical centers and to involve approximately 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 half, the control group, will be treated with chemotherapy agents delivered intravenously. We have identified and approached a number of medical centers that have expressed an interest in conducting the clinical trials. We expect that we will begin to enter into agreements with medical centers to conduct the clinical trials during the year 2002. However, our timetable is subject to uncertainty and we cannot assure you that we can meet our planned schedule. We cannot assure you that all of the medical centers we have identified will be available to conduct the 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 intend to hire a contract research firm to conduct these trials. However, we have not begun negotiations with a contract research organization and we cannot assure you that we will be able to engage an organization on acceptable terms and conditions in a timely manner or at all. The contract research organizations 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 the 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 contract research organization 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 file a submission to seek FDA pre-marketing approval of the Delcath system within 12 to 18 months of the commencement of the clinical trials. However, we may continue to experience delays in beginning, conducting and completing the trials because of factors that include, but are not limited to, delays in designing the trials to conform to the trial protocols, complying with the requirements of institutional review boards at the sites where the trials will be conducted, our ability to identify clinical test sites and sponsoring physicians and the ability of the clinical test sites to identify patients to enroll in the trials. The trials may also take longer to complete because of difficulties we may encounter in entering into agreements with clinical testing sites to conduct the trials and the difficulties these sites may encounter in enrolling patients. Our ability to conduct the trials may also be impaired by our limited experience in arranging for clinical trials and in evaluating and submitting the data gathered from clinical trials. Further, the FDA monitors the progress of the clinical trials and may alter, suspend or terminate the trials based on the data that has been accumulated to that point and its assessment of the relative risks and benefits to the patients involved in the trials.

After acquiring sufficient data, we believe that our collation, analysis and submission of the trial results to the FDA will take an additional three months. Once we submit the data from the clinical trials to the FDA, we estimate that the FDA will respond to our submission within three months. Given the short life expectancy of liver cancer patients, we believe that the FDA will review our pre-market application expeditiously and will respond to our submission within three months. However, the FDA may take longer than three months to evaluate our submission, may require that additional trials be conducted or may not grant approval.

The FDA pre-marketing approval we are currently seeking is limited to administration of doxorubicin with our Delcath system to treatment of patients suffering from metastatic melanoma which has spread to the liver. If we are granted this approval, we plan to subsequently 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.

OUR CLINICAL TRIAL AND AGREEMENT WITH THE NATIONAL CANCER INSTITUTE

In June 2001, the Company announced that The National Institutes of Health/The National Cancer Institute approved a clinical study protocol for administering escalating doses of another chemotherapeutic agent, melphalan hydrochloride ("melphalan") through the Delcath drug delivery system to patients with unresectable cancer of the liver.

The trial conducted at The National Cancer Institute (the "NCI") began in August 2001, and will initially recruit a total of approximately 24 patients, all experiencing metastatic liver cancer. The goal of the trial is to determine the dose limiting toxicity and maximum tolerated dose of melphalan.

This clinical trial, which will include a Phase I and Phase II study, will be undertaken subject to the terms and conditions of the Cooperative Research and Development Agreement (the "CRADA") between the NCI and the Company. FDA approval is necessary to conduct Phase II studies. We cannot estimate how long it will be until we receive FDA approval to commence the Phase II study. The scope of the study is to:

I. Develop a Delcath system-based Phase I treatment protocol for the regional therapy of organs using escalating doses of melphalan hydrochloride delivered through the utilization of the Delcath system. The Phase I study is expected to be completed within one year of the initiation date.

II. Develop Delcath system- based Phase II treatment protocols as a follow-up to Phase I studies. 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 hydrochloride 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 study and take twelve to eighteen months.

The CRADA commits the NCI to perform the research necessary under the Phase I and II protocols approved by the FDA with the Company acting as the sponsor. Delcath will provide funding to the NCI in the amount of $600,000 payable in equal quarterly installments over the five-year term of the agreement unless the CRADA is terminated early. The CRADA can be terminated at any time by either party. In the event of an early termination, Delcath would be responsible for unfunded costs incurred prior to the termination date and all reasonable termination costs. The term of the agreement 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 II trials. An amendment to the CRADA would be necessary if the parties decide to initiate additional clinical trials using another chemotherapeutic agent. The Company is using money raised in its initial public offering to fund this project. If the results of the Phase I and II trials are successful, the Company may need to seek additional capital from investors to pay for the expenses associated with a Phase III clinical trial.

If all three phases of our clinical trials are successful, this will provide us with another chemotherapeutic agent to administer using the Delcath system.

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 41 comprehensive cancer centers in the United States recognized by the National Cancer Institute, beginning with the hospitals participating in the Phase III clinical trials. 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 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. We have not previously sold, marketed or distributed any products and currently do not have the personnel, resources, experience or other capabilities to adequately market the Delcath system. Our success will depend upon our ability to attract and retain skilled sales and marketing personnel. Competition for sales and marketing personnel is intense, and we cannot assure you that we will be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel could adversely affect our business, financial condition and results of operations.

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. However, any revenues we receive from the sale of the Delcath system in foreign markets will depend upon the efforts of these parties and may be less than we would otherwise receive if we marketed the product through our own sales force.

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

Market acceptance of the Delcath system will depend upon:

- the ability of our clinical trials to demonstrate a significant reduction in the mortality rate 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. We only have limited experience in these areas and we cannot assure you that we will be successful in achieving these goals. Moreover, the Delcath system replaces treatment methods in which many hospitals have made a significant investment. Hospitals may be unwilling to replace their existing technology in light of their investment and experience with competing technologies. Many doctors and hospitals are reluctant to use a new medical technology until its value has been demonstrated. As a result, the Delcath system may not gain significant market acceptance among physicians, patients and healthcare payors.

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, which has invested $1,000,000 in Delcath, has previously advised Delcath of its intention to commence clinical trials in Japan. Nissho may also seek to conduct clinical trials in the other countries in the territory.

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

Currently, because the Delcath system is characterized by the FDA as an experimental device, its use is not 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 use of the Delcath system until after its use is approved by the FDA. Even if approved by the FDA, these payors may require us, as a condition to reimbursement, to provide extensive supporting scientific, clinical and cost effectiveness data for our Delcath system to the American Medical Association. New products are under increased scrutiny with respect to a determination as to whether or not they will be covered by the various healthcare plans and with respect to the level of reimbursement which will be applicable to respective covered products and procedures. Third-party payors may deny reimbursement for the treatment and medical costs associated with the Delcath system, notwithstanding FDA or other regulatory approval, if it is determined that the Delcath system is unnecessary, inappropriate, not cost effective, experimental or for a non-approved indication. Third-party payors currently provide reimbursement for many of the components of the Delcath system based on established general reimbursement codes, in connection with their use in liver perfusion and other therapies.

We believe that the Delcath system will provide significant cost savings to the extent that it can reduce treatment and hospitalization costs associated with the side-effects of chemotherapy. Our planned wholesale price for the Delcath system kit is $4,000. A patient normally undergoes four treatments with the Delcath system, each requiring a new system kit. Each treatment with the system costs approximately $12,000, resulting in a total treatment cost of approximately $48,000. This compares to a total 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 produce 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.

The double balloon catheter will be manufactured domestically by the Burron OEM division ("Burron") of B. Braun Medical, Inc. of Germany ("B. Braun"). The double balloon catheter must be manufactured in accordance with manufacturing and performance specifications that are on file with the FDA. Burron has demonstrated that the components it manufactures meet these specifications. Burron's manufacturing facility is ISO 9000 approved, which will allow the use of the catheter 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 Burron to manufacture the catheter either for the clinical trials or for

commercial sale. To ensure sufficient supply of catheters to complete the clinical trials, we intend to purchase our total trial requirements before commencement of the trials.

Medtronic USA, Inc. ("Medtronic") manufactures the components of the blood filtration circuit located outside of the body, including the medical tubing through which a patient's blood flows and various connectors, as well as the blood filtration pump head. Medtronic is a manufacturer of components used for extracorporeal blood circulation during cardiac surgery. The components manufactured by Medtronic have been cleared by the FDA for other applications and can, therefore, be sourced off the shelf. These components, however, must comply with manufacturing and performance specifications for the Delcath system that are on file with the FDA. Medtronic has demonstrated that the components it manufactures meet these specifications. Medtronic's manufacturing facility is also ISO 9000 approved and, thus, the components it manufactures may be used in European markets.

The activated charcoal filters used in the Delcath system are manufactured by Asahi Medical Products of Japan ("Asahi"). These filters have been cleared by the FDA for other applications and can be sourced off the shelf. Asahi has demonstrated that the filters it supplies fall within the performance parameters and meet the specifications on file with the FDA. We have not entered into a written agreement with Asahi to supply the filters either for the Phase III clinical trials or for commercial sale.

We do not have any contracts with suppliers for the manufacture of components for the Delcath system. To date, we have only had components of the Delcath system manufactured for us in small quantities for use in pre-clinical studies and clinical trials. We will require greater quantities for the clinical trials and significantly greater quantities to commercialize the product. If we are unable to obtain adequate supplies of components from our existing suppliers, or need to switch to an alternate supplier, the completion of our clinical trials and commercialization of the Delcath system could be delayed.

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 limited.

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.

Technological developments are expected to continue at a rapid pace in both industry and academia which could result in a short product life cycle for our Delcath system.

GOVERNMENT REGULATION

UNITED STATES FOOD AND DRUG ADMINISTRATION

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, ia a chemotherapy agent that has been approved by the FDA. Like all approved drugs, the approved labeling includes indications for use, method of action, dosing, side-effects and contraindications. Because the Delcath system delivers doxorubicin through a mode of administration and at dose strength that differs from those currently approved, we must obtain approval for revised labeling of doxorubicin and melphalan products permitting their use with the Delcath system. 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.

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:

- the refusal of the government to grant approvals;
- 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 also are 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. It is subject to the most stringent controls applied by the FDA to reasonably assure safety and effectiveness. An application for pre-market approval must be supported by data concerning the device and its components, including the manufacturing and labeling of the device and including the results of animal and laboratory testing and human clinical trials. The conducting of Phase III trials is subject to regulations and to continuing oversight by Institutional Review Boards and 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 signed 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 30 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 and respond to our submission of the Delcath system for commercial sale within three months. 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 bioresearch 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 30 days after the FDA is provided with notice of these changes unless the FDA advises the pre-market approval application holder within 30 days of receipt of the notice that the notice is inadequate or that preapproval 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 promotion 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 device user facility.

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:

- there are in place design controls, including initial design and design changes;
- 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-market 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 to 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 FDA pre-marketing approval of a supplemental or original 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 new drug application for doxorubicin and melphalan to make this change to the labeling of both agents. We are seeking to partner with drug companies for this purpose, but we have no assurance that we will find partners 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, they will 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 the Company's 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 are seeking the approval of institutional review boards at several 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 approvals are obtained, and then only in conformity with conditions of use set forth in the approved labeling.

FOREIGN REGULATION. In order for Nissho or any other 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-market approval or clearance.

In April 1996, FDA legislation was enacted that permits that 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.

We must obtain a CE mark in order for us to market and sell the Delcath system 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 importance on obtaining patent and trade secret protection for significant new technologies, products and processes. We hold the following seven United States patents, as well as three corresponding foreign patents in Canada, Europe and Japan:

Summary Description of Patents	Patent No.
Isolated perfusion method for cancer treatment	U.S. #5,069,662
Isolated perfusion device -- catheter for use in isolated perfusion in cancer treatment	U.S. #5,411,479
Device and method for isolated pelvic perfusion	U.S. #5,817,046
Catheter design to allow blood flow from renal veins and limbs to bypass occluded segment of IVC	U.S. #5,893,841
Balloon inside catheter to restrict blood flow or prevent catheter from moving	U.S. #5,897,533
Catheter with slideable balloon to adjust isolated segment	U.S. #5,919,163
Isolated perfusion method for kidney cancer	U.S. #6,186,146

We plan to vigorously enforce our intellectual property rights. In addition, we will conduct searches and other activity relating to the protection of existing patents and the filing of new applications.

Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation would be costly and divert our attention from our business. If others file patent applications with respect to inventions for which we already have issued patents or have patent applications pending, we may be forced to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which would also be costly and divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources.

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.

PRODUCT LIABILITY

Clinical trials, manufacturing, marketing and product sales may expose us to liability claims from the use of the Delcath system. Though participants in clinical trials are generally required to execute consents and waivers of liability they may still be able to assert product liability claims against us. Claims for damages, whether or not successful, could cause delays in the clinical trials and result in the loss of physician endorsement. We do not currently carry product liability insurance and we may not be able to acquire product liability insurance at sufficient coverage levels or at an acceptable cost. If we are unable to obtain sufficient insurance coverage at an acceptable cost, we may not be able to commercialize the Delcath system. A successful product liability claim or recall would have a material adverse effect on our business, financial condition and results of operations.

EMPLOYEES

As of February 21, 2002, we had six employees all of whom were full-time. 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. Our success will depend, in large part, upon our ability to attract and retain qualified employees. We face competition in this regard from other companies, research institutions and other organizations.

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

ITEM 2. DESCRIPTION OF PROPERTIES.

Delcath currently occupies approximately 3,300 square feet of office space at 1100 Summer Street, Stamford, Connecticut, pursuant to an informal arrangement with the landlord. We have occupied these facilities since 1992, and the space is adequate for our current needs. If we require 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. The Company believes that its properties are adequately covered by insurance.

The Company believes that its facilities and equipment are in good condition and are suitable for its operations as presently conducted and for its foreseeable future operations.

ITEM 3. LEGAL PROCEEDINGS.

The Company is not a party to any litigation.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Company's Common Stock has traded on the Nasdaq National Market under the symbol "DCTHU" from October 19, 2000, the effective date of our registration statement, filed on Form SB-2 under the Securities Act of 1933 (no. 333-39470) relating to our initial public offering of our Common Stock, until October 19, 2001. In

accordance with the terms of our initial public offering, effective October 22, 2001, the Company's common shares and warrants were decoupled from the units issued October 19, 2000 and commenced separate trading. The common shares trade under the sysmbol "DCTH", and the warrants trade under the symbol "DCTHW". The following table sets forth the per share range of high and low sales prices of our Common Stock for the periods indicated:

	Common Stock Price Range	
	2001	
	High	Low
Quarter ended December 31, 2001 (Since October 19 only)	$1.795	$0.56

	Unit Price Range	
	2000	
	High	Low
Quarter ended December 31, 2000	$6.344	$3.313
	2001	
Quarter ended March 31, 2001	$5.69	$2.19
Quarter ended June 30, 2001	$3.20	$1.25
Quarter ended September 30, 2001	$2.92	$1.26
October 1, 2001- October 19, 2001	$1.35	$1.00

As of February 21, 2002, there were approximately 87 stockholders of record of our Common Stock and approximately 730 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.

Use of Proceeds of Initial Public Offering

As noted above, the effective date of our first registration statement, filed on Form SB-2 under the Securities Act of 1933 (no. 333-39470) relating to our initial public offering of our Common Stock, was October 19, 2000. A total of 1,200,000 units were sold for $6.00 per unit, each unit consisting of one share of our Common Stock and one redeemable warrant to purchase one share of our Common Stock for $6.60 per share until October 18, 2005. The initial public offering resulted in gross proceeds of $7.2 million, $720,000 of which was applied toward the underwriting discount. Cash expenses relating to the offering, including a non-accountable expense reimbursement to the underwriters, totaled approximately $1.45 million. Net proceeds to Delcath were approximately $5.4 million. From the time of receipt through December 31, 2001, the net proceeds were applied toward:

Application of Net Proceeds	Approximate Dollar Amount
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin	$1,422,000
Research and development stage clinical trials for other chemotherapy agents	130,000
Repayment of indebtedness	270,000
Working capital and general corporate purposes	283,000
Total	$2,105,000

The remaining net proceeds are being held in temporary investments in short term commercial paper.

ITEM 6. PLAN OF OPERATION.

BACKGROUND

Delcath was founded in 1988 by a team of physicians. Since our inception, 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 in support of the development and the clinical trials of our product. To date, we have been dependent upon the sale of Preferred and Common Stock to fund our activities. Without an FDA-approved product, we have had no commercial sales. We have been unprofitable to date and have had losses of $960,185 and $1,876,007 for the years ended December 31, 2000 and 2001. Included in such losses are non-cash expenses related to the issuance of Common Stock warrants for consulting services. The value of the services is based on the fair value of the warrants on the date of grant using the Black-Scholes pricing model. Cumulative losses from inception through December 31, 2001 were $14,148,154 plus $1,498,605 in accrued Preferred Stock dividends, of which $499,535 was paid in cash and the balance was paid with Common Stock. We expect to incur additional losses over the next three years and anticipate these losses will increase significantly in this period due to continued requirements for product development, clinical studies, regulatory activities, manufacturing and establishment of a sales and marketing organization. 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.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2001, we had $3,295,300 of cash and cash equivalents. As of that date, our principal commitments consisted of $176,080 in accounts payable and accrued expenses. Cash used to fund operations from inception through December 31, 2001 was $11,253,412.

Until completion of its initial public offering, the Company financed its operations primarily through private placements of our Common and Preferred Stock. Prior to the completion of the initial public offering, the Company raised $9,816,686 through the private sale of shares of its Class A Preferred Stock, Class B Preferred Stock and Common Stock. In August and September 2000, the Company also borrowed $230,000 for which it issued $230,000 principal amount of promissory notes, which paid interest at an annual rate of 22% and which were repaid on May 27, 2001. Of these notes, $50,000 in principal amount was subscribed to by M.S. Koly, Chief Executive Officer, President and Director of the Company, and $40,000 principal amount was subscribed to by the mother of Samuel Herschkowitz, M.D., our Chairman of the Board and Chief Technology Officer.

In October 2000, the Company completed an initial public offering. We sold 1,200,000 units for $6.00 per unit, each unit consisting of one share of our Common Stock and one redeemable warrant to purchase one share of our Common Stock for $6.60 per share until October 18, 2005. The Company received $7.2 million before offering costs and before paying cash related to dividends on preferred shares of $499,535. After underwriting discounts and cash expenses of the offering, the net proceeds to us were approximately $5.4 million.

Over the next 12 months, we expect to continue to incur expenses related to the research and development of our technology, including:

- Phase III clinical trials using doxorubicin with the Delcath system.
- Phase I clinical trials using melphalan with the Delcath system.
- 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.

In January 2002, we announced that the New York University School of Medicine plans to proceed with a Phase III study using the Delcath system pending budget approval by NYU and upon approval by NYU's Institutional Review Board. These trials will involve a portion of the total of 122 patients that will participate in the Phase III trials at several institutions, and are expected to take 12 to 18 months to complete. The collation, analysis and submission of the results of the trials to the FDA will take an additional three months and we estimate that the FDA will respond to our submission within three months after that. We cannot estimate when these trials will begin, but we do not expect these trials to begin within the next fiscal year.

We expect to incur significant additional operating losses over each of the next several years and expect cumulative losses to increase significantly as we continue to expand our research and development, clinical trials and marketing efforts. During the next 12 months, we expect to purchase approximately $42,000 in computer, laboratory and testing equipment. We also expect to hire one additional employee in the areas of research and development, regulatory and clinical management. The number and timing of this hiring will vary depending upon the success of the international marketing efforts and progress of the clinical trials.

We currently anticipate that our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures through at least the next 12 months. We may need to raise additional funds prior to the expiration of such period if, for example, we pursue business or technology acquisitions or experience operating losses that exceed our current expectations. If we raise additional funds through the issuance of equity, equity-related or debt securities, such securities may have rights, preferences or privileges senior to those of the rights of our Common Stock and our stockholders may experience additional dilution. We cannot be certain that additional financing will be available to us on favorable terms when required, or at all. Our future liquidity and capital requirements, however, will depend on numerous factors, including:

- the progress of our research and product development programs, including clinical studies;
- the timing and costs of various United States and foreign regulatory filings;
- the timing and effectiveness of product commercialization activities, including marketing arrangements overseas;
- the timing and costs involved in obtaining regulatory approvals, if ever, and complying with regulatory requirements;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the effect of competing technological and market developments.

If our currently available funds are not sufficient to satisfy our spending plans, we will be required to revise our capital requirements or to seek additional funding through borrowings and/or additional sales of securities. We cannot assure you that our available funds will be sufficient to fund our clinical trials with respect to the use of the Delcath system with doxorubicin or melphalan to treat liver cancer. We also cannot assure you that additional financing will become available if needed.

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 and acquisition strategy, our ability to achieve operating efficiencies, our dependence on network infrastructure, capacity, telecommunications carriers and other suppliers, 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 10-QSB/A, Form 8-K and Form 10-KSB reports filed with the Commission.

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 had working capital at December 31, 2001 of $3,189,943. The Company may still require additional working capital in the future and there can be no assurance that such working capital will be available on acceptable terms, if at all. In addition, the Company may need additional capital in the future to fully implement its business strategy as set forth herein.

ITEM 7. FINANCIAL STATEMENTS.

Please refer to pages F-1 through F-14 Independent Auditors' Report Balance Sheet as of December 31, 2001
Statements of Operations for the years ended December 31, 2001 and 2000 (restated) and cumulative from inception (August 5, 1988) to December 31, 2001
Statements of Stockholders' Equity for the years ended December 31, 2001 and 2000 and cumulative from inception (August 5, 1988) to December 31, 2001
Statements of Cash Flows for the years ended December 31, 2001 and 2000 and cumulative from inception (August 5, 1988) to December 31, 2001 Notes to Financial Statements

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

EXECUTIVE OFFICERS, KEY PERSONS AND DIRECTORS

The executive officers and directors of the Company as of February 21, 2001 are as follows:

NAME	AGE	POSITION
M. S. Koly	61	President, Chief Executive Officer, Treasurer and Director
Samuel Herschkowitz, M.D.	52	Chairman and Chief Technology Officer
Thomas S. Grogan	50	Chief Financial Officer

Mark A. Corigliano	38	Director
Daniel Isdaner	37	Director
Victor Nevins	80	Director

M. S. KOLY has been our President, Chief Executive Officer and Treasurer since 1988. In 1988, Mr. Koly was elected to our Board of Directors. From 1987 until June 1998, Mr. Koly managed Venkol Ventures, L.P. and Venkol Ventures, Ltd., firms he co-founded with Dr. Herschkowitz. From 1983 to 1987, Mr. Koly was president of Madison Consulting Corporation, a firm he founded. From 1978 to 1983, Mr. Koly was president of Becton-Dickinson Respiratory Systems. Prior to that time, he held various senior management positions at Abbott Laboratories, Stuart Pharmaceuticals and National Patent Development Corp. He received a B.A. from American University and an M.B.A. in marketing and finance from Northwestern University.

SAMUEL HERSCHKOWITZ, M.D., has been our Chief Technical Officer since 1991. In 1988, Dr. Herschkowitz was elected to be the Chairman of our Board of Directors. In 1987, he co-founded Venkol Ventures L.P. and Venkol Ventures, Ltd., two affiliated venture capital funds specializing in medical technology investments, which are no longer active. Dr. Herschkowitz is board certified in psychiatry and neurology. He is an assistant professor at New York University Medical Center, and has held academic positions at Beth Israel Hospital, Mount Sinai Medical School and Downstate Medical Center. Dr. Herschkowitz graduated from Syracuse University and received his medical degree from Downstate Medical Center College of Medicine.

THOMAS S. GROGAN was appointed the Company's Chief Financial Officer in September 2001. Prior to joining Delcath, Mr. Grogan was V.P. of Business Development for The Jockey Club from 2000-2001. In 1999, he was the Chief Financial Officer for U.S. Homecare Corporation, a publicly traded provider of home healthcare services. From 1998-1999, he was the Chief Financial Officer of the healthcare division of Fairchild Properties, a privately held owner and operator of skilled nursing facilities. From 1993-1998, he was the Chief Financial Officer of NHS National Health Services, Inc., a privately held provider of medical services to corporations, industrial sites and corrections institutions. He is a C.P.A., and holds a B.A. degree from Fordham University and an M.B.A. degree from Cornell University.

MARK A. CORIGLIANO was elected to our Board of Directors in 2001. Since 1991, Mr. Corigliano has been Managing Director of Coast Cypress Associates, a company that designs and implements microcomputer systems. Since 1993, he has served as Officer and Manager of Special Projects for DC Associates, a restaurant management organization located in New York City. He holds a B.S. degree from Seton Hall University.

DANIEL ISDANER was elected to our Board of Directors in 2001. Since 1994, Mr. Isdaner has been the owner and director of Camp Mataponi, Inc., a childrens' summer camp located in Naples, Maine. He also serves on the Board of Directors of the American Camping Association-New England Division and the Jewish Community Center of Southern New Jersey. Mr. Isdaner holds a B.S.B.A. degree from the Boston University School of Management.

VICTOR NEVINS was elected to our Board of Directors in 2001. Since 1957, Mr. Nevins has been Chief Executive Officer of Max Abramson Enterprises, a medium-sized privately held conglomerate headquartered in Flushing, New York. He also is a licensed real estate broker and, in 1962, he founded Victor Nevins Realty. From 1968-1997, he served on the Board of Directors of Flushing Hospital and Medical Center as Vice President of the Board, member of the Finance Committee, Chairman of both the House and Grounds and Human Resources Committees and liaison to the Medical Board. He currently is a Director and past President of the Flushing Chamber of Commerce, a Director of the Flushing Merchants Association, and a Director of the American Red Cross, North Shore Chapter.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires directors, officers, and persons who are beneficial owners of more than ten percent of the Company's Common Stock to file with the Securities and Exchange Commission (the "Commission") reports of their ownership of the Company's securities and of changes in that ownership. To the Company's knowledge, based upon a review of copies of reports filed with the Commission with respect to the fiscal years ended December 31, 2001 and 2000, except as noted below, all reports required to be filed under Section 16(a) by the Company's directors and officers and persons who were beneficial owners of more than ten percent of the Company's Common Stock were timely filed.

Form 4 reports due January 10, 2001 by former directors, William Bergman and James V. Sorrentino and Messrs. Koly and Herschkowitz were inadvertently not timely filed. Such reports were filed in May 2001. Form 3 reports due November 10, 2001 by Messrs. Corigliano, Isdaner and Nevins were inadvertently not timely filed. Such reports were filed in December 2001. Form 3 report due September 25, 2001 by Mr. Grogan was inadvertently not timely filed. This report was filed in January 2002.

The Company is in the process of implementing a Section 16(a) compliance program to assist reporting persons in meeting their reporting obligations in a timely manner.

ITEM 10. EXECUTIVE COMPENSATION.

The following table sets forth, for the fiscal years ended December 31, 2001, 2000, and 1999, certain compensation paid by the Company, including salary, bonuses and certain other compensation, to its Chief Executive Officer and all other executive officers whose annual compensation for the years ended December 31, 2001, 2000, and 1999, exceeded $100,000 (the "Named Executive Officers").

SUMMARY COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($)	SECURITIES UNDERLYING OPTIONS (#)	ALL OTHER COMPENSATION
M. S. Koly	2001	164,750	17,500 (1)	100,000	0
President	2000	98,200	0	102,000	0
	1999	101,250	0	139,746	0
Samuel Herschkowitz	2001	120,000	10,000 (1)	30,000	0
Chairman					

(1) Bonuses were declared payable in January 2002.

OPTION GRANTS IN LAST FISCAL YEAR

Stock options were granted to the Named Executive Officers during the 2001 fiscal year as follows:

NAME	Number of Shares of Common Stock Underlying Option	Percent of Total Options Granted to Employees in 2001	Exercise Price ($/Sh.)	Expiration Date
M. S. Koly	100,000	52.6%	.60	November 2006
S. Herschkowitz	30,000	15.8%	.85	December 2006

AGGREGATED FISCAL YEAR END OPTION VALUES

NAME	Number of Shares of Common Stock Underlying Unexercised Options at December 31, 2001		Value of Unexercised In-the-Money Options at December 31, 2001 (1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
M. S. Koly	86,263	0	0	0
M. S. Koly	53,483	0	0	0
M. S. Koly	102,000	0	0	0
M. S. Koly	0	100,000	0	52,000
S. Herschkowitz	51,757	0	0	0
S. Herschkowitz	32,779	0	0	0
S. Herschkowitz	60,300	0	0	0
S. Herschkowitz	0	30,000	0	8,100

AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

The following table sets forth information with respect to the Named Executive Officers concerning the exercise of options during fiscal years ended December 31, 2001, 2000, and 1999 and unexercised options held as of the end of fiscal 2001.

NAME	YEAR	SHARES TO BE RECEIVED ON EXERCISE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FY-END EXERCISABLE/ UNEXERCISABLE	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FY-END ($) (1) EXERCISABLE/ UNEXERCISABLE
M. S. Koly	2001	0	241,746/100,000	0/52,000
President	2000	0	191,307/50,439	0/0
	1999	0	119,457/20,289	0/0
S. Herschkowitz	2001	0	144,836/30,000	0/8,100
Chairman	2000	0	112,616/32,220	0/0
	1999	0	66,077/18,459	0/0

(1) Calculated based on the fair market value of $1.12 per share at the close of trading on December 31, 2001 as reported by THE WALL STREET JOURNAL, minus the exercise price of the option.

DIRECTOR COMPENSATION

Directors who are employees of Delcath do not currently receive any compensation for serving on the board of directors. Non-employee directors receive $750 for each meeting of the board of directors attended in person or participated in telephonically. In addition, three former non-employee directors each received a one-time option grant in January 1999 of stock options to purchase 34,505 shares of Common Stock at a price of $4.93 per share, all of which have vested. Each one also received a separate one-time option grant in December 1999 of stock options to purchase 22,428 shares of Common Stock at a price of $2.90 per share, all of which have vested.

On November 12, 2001, Delcath's Compensation Committee granted stock options to a director of Delcath, at an exercise price equal to $ .60 per share, the fair market value at the close of trading on that date as reported by THE WALL STREET JOURNAL. On December 17, 2001, Delcath's Compensation Committee granted stock options to directors, at an exercise price of $ .85 per share, the fair market value at the close of trading on that date as reported by THE WALL STREET JOURNAL. The stock options granted to the directors are indicated below:

Name	Incentive Stock Options	Non-Qualified Stock Options
M. S. Koly	100,000	0
Samuel Herschkowitz, M.D.	30,000	0
Mark. Corigliano	0	30,000
D. Isdaner	0	30,000
V. Nevins	0	30,000

STOCK OPTION PLANS

On October 15, 1992, our board of directors and stockholders adopted our 1992 Incentive Stock Option Plan and our 1992 Non-Incentive Stock Option Plan. On June 15, 2000, the board of directors adopted our 2000 Stock Option Plan (the "2000 Plan"). On May 8, 2001, the Board of Directors adopted the 2001 Stock Option Plan (the "2001 Plan"). The 2000 Plan and the 2001 Plan were each approved by the shareholders at the Annual Meeting of Shareholders held on June 12, 2001. On November 13, 2001, our board of directors authorized the amendment of the 2001 Plan to give the Stock Option and Compensation Committee discretion to issue stock options with net issuance provisions. We have reserved 236,359 shares of Common Stock for issuance upon exercise of options granted from time to time under the 1992 Incentive Stock Option Plan, 207,030 shares of Common Stock for issuance upon exercise of options granted from time to time under the 1992 Non-Incentive Stock Option Plan; 300,000 shares of Common Stock for issuance from time to time under the 2000 Plan, and 750,000 shares of Common Stock for issuance from time to time under the 2001 Plan. The stock option plans are intended to assist us in securing and retaining key employees, directors and consultants by allowing them to participate in our ownership and growth through the grant of incentive and non-qualified options.

Under the 1992 Incentive Stock Option Plan we may grant incentive stock options only to employees. Under the 1992 Non-Incentive Stock option Plan, we may grant non-qualified options to our employees, officers, directors, consultants, agents and independent contractors. Under the 2000 and 2001 Plans, we may grant incentive options to employees, and non-incentive options to employees and non-employees including directors, consultants, agents and independent contractors. The stock option plans are administered by the Stock Option and Compensation Committee (the "Committee"), appointed by our Board of Directors.

Subject to the provisions of each of the stock option plans, the Committee will determine who shall receive options, the number of shares of Common Stock that may be purchased under the options, the time and manner of exercise of options and exercise prices. The term of options granted under each of the stock option plans may not exceed ten years, or five years for an incentive stock option granted to an optionee owning more than 10% of our voting stock. The exercise price for incentive stock options shall be equal to or greater than 100% of the fair market value of the shares of the Common Stock at the time granted; provided that incentive stock options granted to an optionee owning more than 10% of our voting stock shall be exercisable at a price equal to or greater than 110% of the fair market value of the Common Stock on the date of the grant. The exercise price for non-qualified options will be set by the committee, in its discretion, but in no event shall the exercise price be less than the fair market value of the shares of Common Stock on the date of grant. Shares of Common Stock received upon exercise of options granted under each of the plans will be subject to restrictions on sale or transfer.

As of December 31, 2001, we have granted incentive stock options to purchase 236,359 shares of Common Stock under our 1992 Incentive Stock Option Plan at a weighted average price of $4.02 and non-incentive stock options to purchase 205,305 shares of Common Stock under our 1992 Non-Incentive Stock Option Plan at a weighted average price of $4.26. All of these options were granted to employees and directors and terminate on the fifth anniversary of their vesting date. We will not grant any additional options under these plans. As of February 21, 2002, we have granted incentive stock options to purchase 150,600 shares of Common Stock under our 2000 Plan at a weighted average price of $2.96 and non-incentive stock options to purchase 133,420 shares, net of 84,000 expired shares, of

Common Stock under our 2000 Plan at a weighted average price of $1.65. As of February 21, 2002, we have granted incentive stock options to purchase 160,000 shares of Common Stock under our 2001 Plan at a weighted average price of $ .69. There have been no awards under our 2001 Plan of non-incentive stock options.

Each of our stock option plans includes a provision that an optionholder, upon exercise of an option, must execute a stockholder's agreement containing provisions to be determined by Delcath at the time of such exercise.

KEY EMPLOYEE AGREEMENTS

On October 30, 2001 the Company amended the Key Employee Agreements dated April 30, 1996, respectively, with M. S. Koly and Samuel Herschkowitz, M.D. Mr. Koly's amendment provides for a base salary of $225,000 per annum, and a lump-sum severance payment of one year's base salary upon notice of termination at any time without cause, and, in the event of termination without cause due to a change in control (as defined) a lump sum severance payment equal to the greater of two years' base salary or the base salary due for the remaining term of the Agreement. The term of the Agreement was extended until December 1, 2004. Dr. Herschkowitz's amendment provides for a base salary of $140,000 per annum

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table sets forth certain information known to the Company regarding the beneficial ownership of the Company's Common Stock as of February 21, 2002, for (i) each stockholder known by the Company to own beneficially 5% or more of the outstanding shares of its Common Stock; (ii) each director; and (iii) all directors and executive officers as a group. The Company believes that the beneficial owners of the Common Stock listed below, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable.

The address for each listed director and officer is c/o Delcath Systems, Inc., 1100 Summer Street, Stamford, Connecticut 06905.

DIRECTORS, EXECUTIVE OFFICERS AND 5% STOCKHOLDERS:	SHARES BENEFICIALLY OWNED	PERCENTAGE OF COMMON SHARES OUTSTANDING
M. S. Koly (4)	1,673,497	40.4%
Venkol Trust (5)	1,374,013	35.2%
Samuel Herschkowitz, M.D. (6)	343,472	8.5%
Frank G. Mancuso, Jr. (7)	110,891	2.8%
James V. Sorrentino, PhD (8)	68,663	1.7%
William I. Bergman (9)	63,833	1.6%
Mark A. Corigliano (10)	-	*
Victor Nevins (11)	-	*
Daniel Isdaner (12)	-	*
Thomas S. Grogan (13)	-	*
All directors and executive officers as a group (nine persons) (14)	2,064,981	46.3%

- ----------------

* Less than 1% of total voting securities

(1) Except as otherwise noted in the footnotes to this table, each person or entity named in the table has sole voting and investment power with respect to all shares owned, based on the information provided to use by the persons or entities named in the table.

(2) Shares of Common Stock subject to options exercisable within 60 days of December 31, 2001 are deemed

outstanding for computing the percentage of the person or entity holding such securities.

(3) Percentage of beneficial ownership is calculated on the basis of the amount of outstanding securities (Common Stock) at December 31, 2001 (3,903,816 common shares) plus, for each person or entity, any securities that person or entity has the right to acquire within 60 days pursuant to stock options or other rights.

(4) Mr. Koly is a director of Delcath. Includes 38,507 shares held by Mr. Koly, and 19,231 shares held by M. Ted Koly, Mr. Koly's minor son. The figure above also includes the vested portion (241,746 shares) of incentive/nonqualified stock options to purchase 114,350 shares of the Company's Common Stock under the Company's 1992 Incentive Stock Option Plan for a weighted average exercise price of $3.98 per share and 25,396 shares of Common Stock under the Company's 1992 Non-Incentive Stock Option Plan for an exercise price of $4.93 per share; and 102,000 shares of Common Stock under the Company's 2000 Stock Option Plan for $3.3125 per share. The figure also includes 1,374,013 shares held by Venkol Trust. The figure above does not include the unvested portion (100,000 shares) of an incentive stock option to purchase 100,000 shares of the Company's Common Stock under the Company's 2001 Stock Option Plan for an exercise price of $0.60 per share.

(5) Mr. Koly is the trustee of Venkol Trust and is deemed the beneficial owner of its shares.

(6) Dr. Herschkowitz is the Chairman of the Board of Directors of Delcath. The figure above includes 17,738 shares held by Dr. Herschkowitz; and an estimated 180,898 shares held by Venkol Trust, as to which Dr. Herschkowitz has a beneficial remainder interest. The Venkol Trust share amount is a maximum estimated distribution because the Venkol Trust has not determined the final distribution amounts. The figure also includes the vested portion (144,836 shares) of an incentive/non-qualified stock options to purchase 75,427 shares of the Company's Common Stock under the Company's 1992 Incentive Stock Option Plan for a weighted average exercise price of $4.05 per share, and 9,109 shares of Common Stock under the Company's 1992 Non-Incentive Stock Option Plan for $4.93 per share; and 60,300 shares of Common Stock under the Company's 2000 Stock Option Plan for an exercise price of $4.93 per share. The figure above does not include the unvested portion (30,000 shares) of an incentive stock option to purchase 30,000 shares of the Company's Common Stock under the Company's 2001 Stock Option Plan for an exercise price of $ .85 per share.

(7) Mr. Mancuso's resigned as a director of the Company on October 1, 2001. The figure above includes an estimated 14,477 shares held by Venkol Trust, as to which Mr. Mancuso has a beneficial remainder interest. The Venkol Trust share amount is a maximum estimated distribution because the Venkol Trust has not determined the final distribution amounts. The figure above also includes 504 shares issuable upon the exercise of warrants at a price of $10.87 per share until April 30, 2002. Also includes the vested portion (56,932 shares) of a non-incentive stock option to purchase 56,932 shares of the Company's Common Stock under the Company's 1992 Non-Incentive Stock Option Plan for a weighted average exercise price of $4.13 per share. Also includes 281,424 shares issuable upon exercise of Warrants.

(8) Mr. Bergman resigned as director on September 21, 2001. Includes vested portion (56,932 shares) of a non- incentive stock option to purchase 56,932 shares of the Company's Common Stock under the Company's 1992 Non-Incentive Stock Option Plan for a weighted average exercise price of $4.13 per share.

(9) Mr. Sorrentino resigned as director on October 26, 2001. Includes vested portion (56,932 shares) of a non- incentive stock option to purchase 56,932 shares of the Company's Common Stock under the Company's 1992 Non-Incentive Stock Option Plan for a weighted average exercise price of $4.13 per share.

(10) Mr.Corigliano is a director of Delcath. Does not include a non-incentive stock option to purchase 30,000 shares of the Company's Common Stock under the Company's 2000 Stock Option Plan for an exercise price of $.85 per share, none of which are vested.

(11) Mr. Isdaner is a director of Delcath. Does not include a non-incentive stock option to purchase 30,000 shares of the Company's Common Stock under the Company's 2000 Stock Option Plan for an exercise price of $.85 per share, none of which are vested.

(12) Mr. Nevins is a director of Delcath. Does not include a non-incentive stock option to purchase 30,000 shares of the Company's Common Stock under the Company's 2000 Stock Option Plan for an exercise price of $.85 per share, none of which are vested.

(13) Mr. Grogan is the Chief Financial Officer of Delcath. Does not include a non-incentive stock option to purchase 30,000 shares of the Company's Common Stock under the Company's 2001 Stock Option Plan for an exercise price of $.85 per share, none of which are vested.

(14) The number of shares beneficially owned by all directors and executive officers as a group includes 1,406,773 shares of Common Stock issuable upon exercise of certain stock options granted to directors and executive officers pursuant to the Company's various Stock Option Plans.

RIGHTS AGREEMENT

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"). A copy of the Rights Agreement is incorporated by reference herein as Exhibit 4.7. 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 dividend was issued on November 14, 2001 to stockholders of record on the Record Date. 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"). The description and terms of the Rights are set forth in the Rights Agreement.

RIGHTS ATTACHED TO COMMON STOCK INITIALLY

Common Stock certificates will evidence the Rights. A notation on the certificates will incorporate the Rights Plan and advise the certificate holder of the existence of the Rights. Until triggered, the Rights are transferred only with the Common Stock certificates. Common Stock certificates issued after November 14, 2001 will contain a legend referencing the existence of a stockholder rights plan. The surrender for transfer of outstanding Common Stock certificates will also constitute the transfer of the Rights associated with the Common Stock.

DISTRIBUTION OF RIGHTS

The Company will mail separate certificates evidencing the Rights to holders of record of the Common Stock on the Distribution Date. The Distribution Date will be the date the Rights separate from the Common Stock, and will be the earlier to occur of the following two events:

- - the close of business on the first day of a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more of the outstanding Common Stock; or

- - 10 business days following the commencement of, or announcement of an intention to make, a tender or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of

such outstanding Common Stock.

As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the Common Stock as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights. The Rights are not exercisable until the Distribution Date. The Rights will expire on October 30, 2011, unless earlier redeemed or extended by the Board.

RIGHT TO PURCHASE COMPANY STOCK

In the event a person becomes the owner of 15% or more of the outstanding shares of Common Stock and thus becomes an Acquiring Person (a "Flip-In Event"), the Rights not held by the Acquiring Person "flip-in" and, instead of continuing as rights to buy one share of Common Stock, become rights to buy from the Company shares of Common Stock having a value equal to two times the Purchase Price of the Right. In other words, a Rights holder (other than the Acquiring Person) may purchase Common Stock at a 50% discount.

In the event there is insufficient Common Stock to permit exercise in full of the Rights, the Company must issue cash, property or other securities of the Company with an aggregate value equal to twice the Purchase Price.

Upon the occurrence of any such Flip-In Event, any Rights owned by an Acquiring Person, its affiliates and associates and certain transferees thereof, shall become null and void.

RIGHT TO PURCHASE ACQUIRING PERSON STOCK

In the event that a person becomes an Acquiring Person, the Company is then merged, and the Common Stock is exchanged or converted in the merger, then each Right (other than those formerly held by the Acquiring Person, which became void) would "flip-over" and be exercisable for a number of shares of Common Stock of the acquiring company having a market value of two times the Purchase Price of the Right. In other words, a Rights holder may purchase the acquiring company's common stock at a 50% discount.

EXCHANGE OF RIGHTS FOR COMMON STOCK

After a Flip-In Event but before a "flip-over" event (as described above) occurs and before an Acquiring Person becomes the owner of 50% or more of the Common Stock, the Board may cause the Rights (either in whole or in part) to be exchanged for shares of Common Stock (or equivalent securities, of equal value) at a one-to-one exchange ratio or pursuant to an equivalent cashless exercise method. Rights held by the Acquiring Person, however, which became void upon the Flip-In Event, would not be entitled to participate in such exchange.

REDEMPTION

The Rights may be redeemed by the Board at a redemption price of $0.01 per Right at any time prior to the earlier of:

- - the time that a person or a group becomes an Acquiring Person, or

- - October 30, 2011, the expiration date of the Rights Agreement.

Immediately upon redemption and without further action and without any notice, the right to exercise the Rights will terminate and the only right of the holders will be to receive the redemption price.

EXPIRATION OF RIGHTS

The Rights will expire on October 30, 2011, unless the expiration date is extended by amendment or unless the Rights are earlier redeemed or exchanged by the Company as described above.

AMENDMENTS OR SUPPLEMENTS

For so long as the Rights are redeemable, the terms of the Rights may be amended or supplemented by the Board of Directors at any time and from time to time without the consent of the holders of the Rights. At any time when the Rights are not redeemable, the Board of Directors may amend or supplement the terms of the Rights, provided that such amendment does not adversely affect the interests of the holders of the Rights.

NO RIGHTS AS STOCKHOLDERS

Until a Right is exercised, the holder thereof will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

MISCELLANEOUS

In order to prevent dilution, the Purchase Price, the number of Common Stock or other securities or property purchasable upon exercise of each Right and the number of Rights outstanding are subject to adjustment from time to time as provided in the Rights Agreement.

The Company is not required to issue fractions of Rights or to distribute Right Certificates which evidence fractional Rights (except as may be provided for in the Rights Agreement). In lieu of such fractional Rights, the Company will pay to the registered holders of the Right Certificates with regard to which such fractional Rights would otherwise be issuable, an amount of cash equal to the same fraction of the current market value of a whole Right.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

All of our preferred stockholders converted their Preferred Stock into 833,873 shares of Common Stock. The preferred stockholders also accepted 690,910 shares of Common Stock as payment of $999,070 of accumulated dividends, and a cash dividend of $499,535 as payment of the balance of the accrued dividend. Venkol Trust held all 2,000,000 shares of our class A Preferred Stock and received 690,099 shares of Common Stock on conversion of those shares, 616,127 shares of Common Stock in partial payment of accumulated dividends and a cash dividend of $223,202 in payment of the balance of the accrued dividend. Frank Mancuso, Jr. and Venkol Trust owned 19,608 and 117,650 shares of our class B Preferred Stock and received 6,766 and 40,595 shares of Common Stock, upon conversion of those shares, 3,519 shares and 21,115 shares of Common Stock in payment of $26,008 and $156,048 of accumulated dividends and cash dividends of $13,004 and $78,024, as payment of the balance of the accrued dividends.

In April 2000, we issued 230,873 shares of Common Stock to existing security holders and their designees for proceeds of $501,825 in a rights offering. Each of M.S. Koly, Samuel Herschkowitz, our Chairman and Chief Technical Officer, and James Sorrentino, a director of Delcath, purchased 11,732 shares for $25,500, and William Bergman, a director of Delcath, purchased 6,901 shares for $15,000.

In August and September 2000, Delcath borrowed an aggregate of $230,000 for which it issued promissory notes due on May 27, 2001. The promissory notes bear interest at an annual rate of 22%. Of these loans, $205,000 was borrowed from existing stockholders or relatives of existing stockholders of Delcath. M.S. Koly, Chief Executive Officer, President and a director of Delcath, and Mary Herschkowitz, the mother of Samuel Herschkowitz, M.D., Chairman and Chief Technical Officer of Delcath, provided $50,000 and $40,000 of the loans.

We believe that each of the transactions with our officers, directors and principal stockholders and their affiliates were on terms no less favorable than could have been obtained from unaffiliated third parties. All future transactions, including loans between us and our officers, directors and stockholders beneficially owning 5% or more of our outstanding voting securities, or their affiliates, will be on terms no less favorable to us than could be obtained in arm's length transactions from unaffiliated third parties. Further, all transactions and loans and any forgiveness of indebtedness owed by any of our officers, directors and stockholders beneficially owning 5% or more of our outstanding voting securities, or their affiliates, to us, must be approved by a majority of our independent directors

who do not have an interest in the transactions and who have access, at our expense, to either our legal counsel or independent legal counsel.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

(a) EXHIBITS

Except where indicated, the following exhibits were previously filed in connection with the Company's Registration Statement on Form SB-2, Registration No. 333-39470 or subsequent periodic reports, and are incorporated by reference.

Exhibit Number	Description
1.1	Form of Underwriting Agreement
3.1	Revised form of Amended and Restated Certificate of Incorporation of the Registrant
3.2	Revised form of By-Laws of the Registrant
4.1	Specimen Stock Certificate
4.2	Form of Underwriter's Warrant Agreement
4.3	Warrant Agreement among Registrant, Underwriter and Transfer Agent
4.4	Specimen Redeemable Warrant
4.5	Warrant Agreement between the Registrant and Euroland Marketing Solutions, Ltd.
4.6	Warrant No. W-2 to purchase up to 150,000 units granted to Euroland Marketing Solutions, Ltd.
4.7	Rights Agreement dated October 30, 2001
5.1	Opinion of Morse, Zelnick, Rose & Lander, LLP
10.1	1992 Incentive Stock Option Plan
10.2	1992 Non-Incentive Stock Option Plan
10.3	2000 Stock Option Plan
10.4	Employment Agreement between the Registrant and M.S Koly, as amended
10.5	Employment Agreement between the Registrant and Samuel Herschkowitz, M.D., as amended
10.6	Distributorship Agreement with Nissho Corporation
10.7	Form of Lock-up Agreement
10.8	Form of Promissory Note
10.9	Consulting Services Agreement between the Registrant and Euroland Marketing Solutions, Ltd.
10.10	Amendment to Key Employee Agreement between the Registrant and M. S. Koly dated October 30, 2001
10.11	Amendment to Key Employee Agreement between the Registrant and Samuel Herschkowitz, M.D. dated October 30, 2001
10.12	2001 Stock Option Plan
10.13(*)	Engagement Agreement between the Registrant and Redington Inc. for the period from November 1, 2000-October 31, 2001
24	Power of Attorney (included in signature page). (*)

(*) Filed herewith.

(b) REPORTS ON FORM 8-K

No reports on Form 8-K were filed by the Company during the Company's fiscal quarter December 31, 2001.

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 11, 2002

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 11, 2002
/s/ Thomas S. Grogan Thomas S. Grogan	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2002
/s/ Samuel Herschkowitz, M.D. Samuel Herschkowitz, M.D.	Chairman of the Board	March 11, 2002
/s/ Mark Corigliano Mark A. Corigliano	Director	March 11, 2002
/s/ Daniel Isdaner Daniel Isdaner	Director	March 11, 2002
/s/ Victor Nevins Victor Nevins	Director	March 11, 2002

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 enterprise) as of December 31, 2001 and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2001 and for the period from August 5, 1988 (inception) to December 31, 2001. 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 referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. (a development stage enterprise) as of December 31, 2001 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2001 and for the period August 5, 1988 (inception) to December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 (g) to the financial statements, Delcath Systems, Inc. has restated the net loss attributable to common stockholders and the loss per share for the year ended December 31, 2000 to give effect to preferred stock dividends paid in common stock.

KPMG LLP

New York, NY
February 22, 2002

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Balance Sheet

Assets	December 31, 2001
Current assets:	
Cash and cash equivalents	$ 3,295,300
Interest receivable	1,056
Prepaid insurance	69,667
Total current assets	3,366,023
Furniture and fixtures, net	13,496
Due from affiliate	24,000
Total assets	$ 3,403,519
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable and accrued expenses	$ 176,080
Total current liabilities	176,080
Stockholders' equity (note 2):	
Preferred stock, $.01 par value: 10,000,000 shares authorized; no shares issued and outstanding	-
Common stock, $.01 par value; 15,000,000 shares authorized; 3,903,816 shares issued and outstanding	39,038
Additional paid-in capital	18,835,160
Deficit accumulated during development stage	(15,646,759)
Total stockholders' equity	3,227,439
Total liabilities and stockholders' equity	$ 3,403,519

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Operations

	Years ended December 31,		Cumulative from inception (August 5, 1988) to December 31, 2001
	2000 (Restated)	2001	
Costs and expenses:			
Legal, consulting and accounting fees	$ 474,061	1,034,025	6,025,255
Stock option compensation expense	--	--	2,520,170
Compensation and related expenses	259,446	557,087	3,304,703
Other operating expenses	298,204	477,544	2,967,024
Total costs and expenses	1,031,711	2,068,656	14,817,152
Operating loss	(1,031,711)	(2,068,656)	(14,817,152)
Interest income	94,555	208,220	840,471
Interest expense	(23,029)	(15,571)	(171,473)
Net loss	(960,185)	(1,876,007)	(14,148,154)
Preferred stock dividends paid in common stock	(999,070)	--	
Preferred stock dividends paid in cash	(499,535)	--	
Net loss attributable to common stockholders	$(2,458,790)	$(1,876,007)	
Common share data:			
Basic and diluted loss per share	$ (1.52)	$ (0.48)	
Weighted average number of basic and diluted common stock outstanding	1,621,723	3,903,816	

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.
(A DEVELOPMENT STAGE COMPANY)

Statements of Stockholders' Equity

Years ended December 31, 2001 and 2000 and
cumulative from inception (August 5, 1988) to December 31, 2001

	Common stock $.01 par value					
	Issued		In treasury		Outstanding	
	No. of shares	Amount	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988	621,089	$ 6,211	--	$ --	621,089	$ 6,211
Sale of preferred stock, August 22, 1988	--	--	--	--	--	--
Shares returned as of March 9, 1990	--	--	(414,059)	(4,141)	(414,059)	(4,141)
Sale of stock, October 2, 1990	--	--	17,252	173	17,252	173
Sale of stock, January 23, 1991	--	--	46,522	465	46,522	465
Sale of stock, August 30, 1991	--	--	1,353	14	1,353	14
Sale of stock, December 31, 1992	--	--	103,515	1,035	103,515	1,035
Sale of stock, July 15, 1994	--	--	103,239	1,032	103,239	1,032
Sale of stock, December 19, 1996	--	--	39,512	395	39,512	395
Shares issued in connection with conversion of short-term borrowings as of December 22, 1996	58,491	585	98,388	984	156,879	1,569
Sale of stock, December 31, 1997	53,483	535	--	--	53,483	535
Exercise of stock options	13,802	138	3,450	35	17,252	173
Shares issued as compensation	2,345	23	828	8	3,173	31
Amortization of compensatory stock options granted	--	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--	--
Shares issued in connection with exercise of warrants	21,568	216	--	--	21,568	216
Sale of stock, January 16, 1998	34,505	345	--	--	34,505	345
Sale of stock, September 24, 1998	3,450	35	--	--	3,450	35
Shares returned, April 17, 1998	(3,450)	(35)	--	--	(3,450)	(35)
Amortization of compensatory stock options granted	--	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--	--
Exercise of stock options	8,626	86	--	--	8,626	86
Sale of stock, June 30, 1999	46,987	470	--	--	46,987	470
Amortization of compensatory stock options granted	--	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--	--
Shares issued in connection with exercise of warrants	2,300	23	--	--	2,300	23
Deficit accumulated from inception to December 31, 1999	--	--	--	--	--	--
Balance at December 31, 1999	863,196	8,632	--	--	863,196	8,632
Sale of stock, April 14, 2000	230,873	2,309	--	--	230,873	2,309
Dividends paid on preferred stock	690,910	6,909	--	--	690,910	6,909
Conversion of preferred stock	833,873	8,339	--	--	833,873	8,339
Sale of stock, October 19, 2000	1,200,000	12,000	--	--	1,200,000	12,000
Shares issued as compensation for stock sale	85,000	850	--	--	85,000	850
Stock options issued as compensation	--	--	--	--	--	--
Net loss for year ended December 31, 2000	--	--	--	--	--	--
Balance at December 31, 2000	3,903,852	39,039	--	--	3,903,852	39,039
Sum of fractional common shares cancelled after year 2000 stock splits	(36)	(1)	--	--	(36)	(1)
Stock warrants issued as compensation	--	--	--	--	--	--
Net loss for year ended December 31, 2001	--	--	--	--	--	--
Balance at December 31, 2001	3,903,816	$ 39,038	--	$ --	3,903,816	$ 39,038

	Preferred Stock		Class A preferred stock		Class B preferred stock	
	$.01 par value		$.01 par value		$.01 par value	
	No. of shares	Amount	No. of shares	Amount	No. of shares	Amount
Shares issued in connection with the formation of the Company as of August 22, 1988	--	$ --	--	$ --	--	$ --
Sale of preferred stock, August 22, 1988	--	--	2,000,000	20,000	--	--
Shares returned as of March 9, 1990	--	--	--	--	--	--
Sale of stock, October 2, 1990	--	--	--	--	--	--
Sale of stock, January 23, 1991	--	--	--	--	416,675	4,167
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	--	--	--	--	--	--
Deficit accumulated from inception to December 31, 1999	--	--	--	--	--	--
Balance at December 31, 1999	--	--	2,000,000	20,000	416,675	4,167
Sale of stock, April 14, 2000	--	--	--	--	--	--
Dividends paid on preferred stock	--	--	--	--	--	--
Conversion of preferred stock	--	--	(2,000,000)	(20,000)	(416,675)	(4,167)
Sale of stock, October 19, 2000	--	--	--	--	--	--
Shares issued as compensation for stock sale	--	--	--	--	--	--
Stock options issued as compensation	--	--	--	--	--	--
Net loss for year ended December 31, 2000	--	--	--	--	--	--
Balance at December 31, 2000	--	--	--	--	--	--
Sum of fractional common shares cancelled after year 2000 stock splits	--	--	--	--	--	--
Stock warrants issued as compensation	--	--	--	--	--	--
Net loss for year ended December 31, 2001	--	--	--	--	--	--
Balance at December 31, 2001	--	$ --	--	$ --	--	$ --

	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 9, 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	--	2,496,347
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	--	1,166,418
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
Deficit accumulated from inception to December 31, 1999	--	(11,311,962)	(11,311,962)
Balance at December 31, 1999	11,767,236	(11,311,962)	488,073
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
Net loss for year ended December 31, 2000	--	(960,185)	(960,185)
Balance at December 31, 2000	18,637,159	(13,770,752)	4,905,446
Sum of fractional common shares cancelled after year 2000 stock splits	1	--	--
Stock warrants issued as compensation	198,000	--	198,000
Net loss for year ended December 31, 2001	--	(1,876,007)	(1,876,007)
Balance at December 31, 2001	$ 18,835,160	$(15,646,759)	$ 3,227,439

See accompanying notes to financial statements.

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statement of Cash Flows

	Years ended December 31,		Cumulative from inception (August 5, 1988) to
	2000	2001	December 31, 2001
Cash flows from operating activities:			
Net loss	$ (960,185)	$ (1,876,007)	$(14,148,154
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	--	--	2,520,170
Stock, option and warrant compensation expense issued for consulting services	3,800	198,000	236,286
Depreciation expense	3,000	5,014	14,764
Amortization of organization costs	--	--	42,165
Increase decrease in prepaid expenses	(64,999)	(501)	(69,667)
(Increase) decrease in interest receivable	(29,042)	31,312	(1,056)
Due from affiliate	--	--	(24,000)
(Decrease) increase in accounts payable and accrued expenses	686,167	(622,835)	176,080
Net cash used in operating activities	(361,259)	(2,265,017)	(11,253,412)
Cash flows from investing activities:			
Purchase of furniture and fixtures	--	(13,260)	(28,260)
Purchase of short-term investments	--	--	(1,030,000)
Proceeds from maturities of short-term investments	--	--	1,030,000
Organization costs	--	--	(42,165)
Net cash used in investing activities	--	(13,260)	(70,425)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	5,873,293	--	13,413,708
Dividends paid	(499,535)	--	(499,535)
Proceeds from (Repayments) short-term borrowings	230,000	(230,000)	1,704,964
Net cash provided by financing activities	5,603,758	(230,000)	14,619,137
Increase (decrease) in cash and cash equivalents	5,242,499	(2,508,277)	3,295,300
Cash and cash equivalents at beginning of period	561,078	5,803,577	--
Cash and cash equivalents at end of period	$ 5,803,577	3,295,300	$ 3,295,300
Cash paid for interest	$ 23,029	36,141	$ 171,473
Supplemental non-cash activities:			
Conversion of debt to common stock	$ --	--	$ 1,704,964
Common stock issued for preferred stock dividends	$ 999,070	--	$ 999,070
Conversion of preferred stock to common stock	$ 24,167	$ --	$ 24,167
Common stock issued as compensation for stock sale	$ 510,000	$ --	$ 510,000
Stock, options and warrants issued as compensation for consulting services	$ 3,800	$ 198,000	$ 236,286

See accompanying notes to financial statements.

(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 FDA pre-marketing approval for the use of its delivery system using doxorubicin, a chemotherapeutic agent, to treat malignant melanoma that has spread to the liver.

(b) BASIS OF FINANCIAL STATEMENT PRESENTATION

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles. The preparation of financial statements in conformity with generally accepted 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 over the estimated useful lives of the assets of five years. Accumulated depreciation amounted to $14,764 at December 31, 2001.

(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. 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 and pro forma earnings 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 provisions of SFAS No. 123 (see note 2(b)).

(f) LOSS PER SHARE

The Company follows the provisions of SFAS 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. We have excluded certain Common Stock equivalents from our diluted EPS calculation for all years presented as their effect would have reduced our net loss per share.

(g) RESTATEMENT OF NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS AND LOSS PER SHARE FOR 2000

Loss per share for the year ended December 31, 2000 has been restated from $ (.90) per share as previously reported to $(1.52) per share and net loss attributable to common stockholders for the year ended December 31, 2000 has been restated from $ (1,459,720) as previously reported to $(2,458,790) to give effect to $999,070 of preferred stock dividends that were paid in Common Stock in 2000. The effect of such dividends paid in Common Stock on the loss attributable to common stockholders was not included in the computation underlying the previously reported amount for 2000.

(h) STATEMENTS OF CASH FLOWS

For purposes of the statements of cash flows, the Company considers highly liquid debt instruments with original maturities of three months or less to be cash equivalents. At December 31, 2001 cash equivalents included commercial paper of $1,741,571.

(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 exchanged 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 to 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 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.

Effective May 7, 1990, the Company changed its name to Delcath Systems, Inc.

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 $1,401,566. 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 our 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 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 expire 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") underwritten by Whale Securities Co., L. P. 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 Whale Securities Co., L. P. 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 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 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 Delcath Common Stock for $6.60 per share. None of these warrants have been exercised as of December 31, 2001. Such warrants, valued at $175,000, were recognized as an expense in the first quarter of 2001; and (2) 150,000 warrants to purchase up to 150,000 shares of Delcath Common Stock, through April 30, 2005, for $6.60 per share. None of these warrants have been exercised as of December 31, 2001. 25,000 of such warrants vested in 2001 and the remaining 125,000 warrants vest if the share price of the Company's Common Stock exceeds certain share price levels above the IPO price. As of December 31, 2001, none of the thresholds have been met. Such remaining warrants will not vest if the conditions are not met by May 2002. 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 above, recognized with these two warrant issues are non-cash expenses.

The value 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 which represented the total of fractional shares resulting from year 2000 stock splits.

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.

The two affiliated venture capital funds discussed above were liquidated in 1998 and the shares of the Company then owned by the funds were distributed to the individual investors of the funds, or their nominee, if so directed.

(b) STOCK OPTION PLANS

The Company established an Incentive Stock Option Plan and a Non-Incentive Stock Option Plan under which stock options may be granted. Additionally, the Company has entered into separate contracts apart from the Incentive Stock Option Plan and the Non-Incentive Stock Option Plan 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 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 Plans were approved and became effective on November 1, 1992. During 2000 and 2001, respectively, the 2000 and 2001 Stock Option Plans became effective. The Incentive Stock Options 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, 2000 through December 31, 2001 is as follows:

	NON-INCENTIVE AND INCENTIVE OPTION PLANS		OTHER OPTION GRANTS	
	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding at December 31, 1999	441,664	$ 4.13	17,252	$ 2.90
Granted during 2000	248,020	3.31	--	--
Outstanding at December 31, 2000	689,684	3.82	17,252	2.90
Granted during 2001	280,000	.83	--	--
Expired during 2001	(84,000)	3.31	--	--
Outstanding at December 31, 2001	885,684	$ 2.94	17,252	$ 2.90

The following summarizes information about shares subject to option at December 31, 2001:

OPTIONS OUTSTANDING				OPTIONS EXERCISABLE	
NUMBER OUTSTANDING	RANGE OF EXERCISE PRICES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING LIFE IN YEARS	NUMBER EXERCISABLE	WEIGHTED AVERAGE EXERCISE PRICE
100,000	$ .60	$ .60	4.92	-	-
150,000	.85	.85	5.00	-	-
30,000	1.53	1.53	4.67	-	-
189,777	2.90	2.90	3.00	189,777	$ 2.90
164,020	3.31	3.31	3.95	164,020	3.31
269,139	4.93	4.93	2.00	269,139	4.93
902,936	$ .60 - $4.93	$2.94	3.47	622,936	$3.89

The Company applies APB 25 and related interpretations in accounting for its plans. As such, compensation cost is measured at the date of grant as the excess, if any, of the fair market value of the underlying stock over the exercise price. Such cost is then recognized over the period the recipient is required to perform services to earn such compensation. If a stock option is not exercised 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. Stock option compensation expense associated with the Incentive and Non-Incentive Stock Plans for the years ended December 31, 2000 and 2001 was $3,800 and $ -, respectively. 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 123, the Company's net loss

and net loss per share for the years ended December 31, 2000 and 2001 would have been increased to the pro forma amounts indicated as follows:

	2000	2001
Net loss:		
As reported	$ (960,185)	$(1,876,007)
Pro forma	(1,431,352)	(2,186,270)
Basic and diluted loss per share		
As reported (Restated for 2000)	$ (1.52)	$ (0.48)
Pro forma (Restated for 2000)	(1.75)	(0.56)

The per share weighted average fair value of stock options granted during 2000 and 2001 were $2.21 and $.30, 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 2000 and 2001 , respectively: risk free interest rates of 6.5% and 3.6% - 4.95%, respectively, and volatility of 76.7% and 26.7% - 36.3%, respectively, while no dividend yield and expected lives of five years were assumed for both years.

(3) INCOME TAXES

As of December 31, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately $11,109,000 which are available to offset future federal taxable income, if any, through 2021. The net operating loss carryforwards resulted in a deferred tax asset of approximately $3,777,000 at December 31, 2001 ($3,209,000 at December 31, 2000). Management does not expect the Company to be taxable in the near future and established a 100% valuation allowance against the deferred tax asset created by the net operating loss carryforwards at December 31, 2001 and 2000.

(4) DUE FROM AFFILIATE

The Company sublets office space from an affiliate pursuant to an informal arrangement. In addition, the Company paid the affiliate $24,000, which the affiliate then paid to the landlord as a deposit on the lease.

EXHIBIT 10.13

Redington, Inc.

Engagement Agreement
Delcath Systems, Inc.
FIVE PAGES IN ALL

DELCATH SYSTEMS, INC. ("CLIENT") HAS ENGAGED REDINGTON, INC.("REDINGTON"), A CONNECTICUT CORPORATION, TO PERFORM CERTAIN INVESTOR RELATIONS SERVICES OUTLINED BELOW BETWEEN NOVEMBER 1, 2000 AND OCTOBER 31, 2001 AND WHICH MAY BE AGREED FROM TIME TO TIME IN THE FUTURE BY BOTH PARTIES.

REDINGTON WILL IMPLEMENT THE FOLLOWING PROGRAMS AND ACTIVITIES WHICH ARE MORE FULLY DESCRIBED IN THE SHEET ENTITLED "PROGRAM ELEMENTS" ATTACHED HERETO AS EXHIBIT A:

1. Production and distribution of Delcath At A Glance.

2. Outbound/Inbound contacts in the total amount of 600 hours by the Redington Investor Contact Unit (ICU) to the Redington Retail Database over the 12-month program period with a planned utilization of 100-125 hours monthly during the first three months of the program.

3. Advise on Delcath investor presentation; revise road show deck.

4. Staging of investor road shows in twelve US markets.

5. Editing of corporate news release during program period.

6. Senior staff services as budgeted for above items 2, 3, 5 and counseling and advice on all investor/financial communications programs and issues during program period.

AGENCY PROFESSIONAL SERVICES:

COSTS FOR ON-GOING AGENCY PROFESSIONAL SERVICES TOTAL $52,000, AND COSTS FOR SERVICES FOR SPECIAL PROJECTS TOTAL $68,000, OR A TOTAL OF $120,000 AS FOLLOWS:

1. $36,000 for Redington Investor Contact Unit (ICU) outbound/inbound broker contract program; average 50 hours monthly (total 600 hours) at $000/hr. vs. normal rate of $125/hr.

2. $16,000 for 00 hours program management, counseling, client meetings, reports, correspondence, editing of news releases, billed at $000/hr vs. normal rate of $250/hr.

3. $60,000 for audience development, logistical staging and on-site management of twelve market road shows.

4. $8,000 for research, writing, editing, production supervision of Delcath At A Glance.

AGENCY SERVICES FOR SENIOR STAFF AND ICU (#1 AND #2 ABOVE) ARE BILLED IN ADVANCE MONTHLY ($4,333) AND AGENCY SERVICES FOR SPECIAL PROJECTS (#3 AND #4) ARE BILLED ONE-HALF IN ADVANCE AND ONE-HALF ON COMPLETION. STATE SALES TAXES MAY APPLY TO THESE CHARGES.

OUT-OF-POCKET DISBURSEMENTS:

For the 12 month period in the following approximate categories and allocations:

Typesetting/Printing At A Glances	$ 6,500
Mail AAGs/Kits/Invites	8,000
Meeting Hospitality/AV 12 Mtgs/$2,500 Avg. Ea.	30,000
Long Distance Telephone - Meetings	4,200
Long Distance Telephone - Ongoing	4,800
FAX/FAX Broadcast	4,500
FedEx	2,500
Agency Travel	6,500
Contingencies	6,000
Total Disbursements:	$73,000

DISBURSEMENTS ARE BILLED MONTHLY AS INCURRED OR EARLIER IN THE CASE OF COMPLETED SPECIAL PROJECTS. LONG DISTANCE PHONE IS BILLED AT A FLAT RATE OF $350 MONTHLY AND $400 FOR EACH ROAD SHOW.

COMPENSATION PROVISIONS

Agency services compensation under this program totaling $191,000 will be paid net 10 days to Redington as provided for herein.

All out-of-pocket disbursements incurred by Redington on behalf of Client will be paid net 10 days to Redington as provided for herein. The

disbursement budget in this agreement is approximate to the best of Redington's ability to estimate such expenses in advance of project execution. No expenses beyond the total presented in said budget will be committed without prior written approval of Client.

INCENTIVE COMPENSATION PROVISIONS

Client will issue Redington a warrant (the "Incentive Warrant") upon execution of this agreement for the purchase of $150,000 shares of Client Common Stock at an exercise price of $6.60 (Base Price) for five years with cashless exercise and ownership transfer provisions. The Incentive Warrant, which expires on April 30, 2005, vests as follows:

1. 25,000 shares upon start of program
2. 50,000 shares upon meeting call provisions of the IPO Unit Warrants
3. 25,000 shares upon share price goal of 75% above the Base Price
4. 12,500 shares upon share price goal of 100% above the Base Price
5. 37,500 shares upon share price goal of 75% above the Base Price

All provisions of the first vesting event (25,000 warrants) are met upon execution of this agreement.

All provisions of the second vesting event (50,000 warrants) are met when the call provisions of the Warrants issued as part of the Client's IPO Unit offering are met, whether or not client elects or is able to execute the call. If provisions of the second vesting event are met, Client additionally agrees to make payment to Redington of either $125,000 or 20,000 fully paid shares of Client common stock. The choice of payment is the decision of Redington if 75 percent or more of subject warrants are exercised, or if less than 75 percent of subject warrants are exercised , the choice of payment is the decision of the Client. Whichever the outcome, the payments to Redington will be made to within 15 days of the second vesting event's provisions being met.

All provisions of the third and fourth vesting events (37,500 shares) are deemed met when the average closing price on the principal exchange of trading the company's shares is at or above the goal on eight of any 10 consecutive trading days between the dates of November 1, 2000 and April 30, 2002.

All provisions of the fifth vesting event (37,500 shares) are deemed met when the average closing price on the principal exchange of trading the company's shares is at or above the goal during the last three weeks of the 12th month and the first week of the 13th month following the effective date of the client IPO, or if 50 percent or more of the so-called "Founder's" shares to have been sold in a private or best-efforts, or underwritten

transaction at any price by the end of the 14th week following the effective date of the Client IPO.

Any of the above goals can be met sequentially or simultaneously.

The actual number of shares of Common Stock awarded under this program will be adjusted for any stock splits and the rights of the warrant holder with regard to any dividends or any restructuring will be the same as if the warrant holder held the shares of Common Stock underlying the warrants at the time of any such actions.

Client agrees to use its best efforts to provide freely tradable shares upon exercise of any part of Incentive Warrant described above or the issuance of any fully paid for Client shares and will provide piggy back registration of said shares on any registration of shares Client may undertake for other parties. If no such registration occurs within one month of any vesting of the Incentive Warrants or payment to Redington of any fully paid for Client shares, Redington can demand Client to file for registration of such shares by any means available which Client agrees to support in all respects so that a registration of Redington's shares can proceed in a timely manner. The costs of a demand registration, exclusive of costs incurred by Client in preparation of customary or other documents issuer's are or may be required to provide for such a registration, will be born by Redington unless any other warrant or shareholder of Client seeks piggyback registration with the Redington registration, in which case all reasonable costs of the registration, including all reasonable costs already incurred by Redington or its agents, will be paid by Client. Client agrees these registration provisions will not be subordinated or otherwise changed, overridden or mitigated by any historic or future agreements or occurrences unless written approval of Redington and that any disputes will be resolved as provided for herein.

OTHER PROVISIONS

The intent of this program is to broaden sponsorship of Client in the US financial community; however, no assurances can be given that the desired result will be achieved, it being a function of many factors, most of which are not controllable by either the Client or Redington

- Client agrees that the Redington financial community database is Redington property and will be available for Client use and activities only during the term of this agreement.

- Client acknowledges that Redington mastheads (i.e., At A Glance, Preview, Profile and other similar mastheads that may be developed) are exclusive and will be available for client use only during this agreement; Client, however, is deemed to own the text developed for

it by Redington and is free to use it at will after the expiration or termination of this program, assuming all Client financial obligations to Redington are met

- Redington will exercise its best professional efforts in execution of this program.

- Client will advise Redington immediately in writing of any material change in its business and, in particular, any changes that may influence an investor's decision to either buy, hold or sell Client securities.

- Client agrees to hold Redington harmless against any action (whether or not in connection with litigation in which Redington is a party) resulting form dissemination of Client-approved written information or oral information consistent in all material respects with such written information, including any legal fees or other costs that may be reasonably incurred by Redington in defense of any such actions, or in giving testimony or furnishing documents in response to a subpoena or otherwise. Redington will give Client prompt notice of any claim asserted or threatened against Redington on the basis of which Redington intends to be held harmless as herein provided. Client may also participate at its own expense in the defense of such action.

- Redington will not disseminate written information about Client without prior written approval from Client.

- Either party may cancel this agreement and the cash compensation provisions on 45 days written notice. The provisions of the "Incentive Warrant's" vesting schedule will survive termination of this agreement for 90 days after written notification of such termination by either party.

- Redington invoices are payable net 10 days upon presentation with interest of 1.5 percent on any amounts due past 30 days. In the event any dispute, controversy or claim between the parties arises out of the subject matter of this agreement or its interpretation, it shall be settled by arbitration taking place in New York, New York by a sole arbitrator acting under and pursuant to the Rules of Commercial Arbitration of the American Arbitration Association. Any award rendered shall be final and conclusive upon the parties, and a judgment thereon may be entered in the highest court of the forum, whether state or federal, having jurisdiction. The party ultimately prevailing shall be entitled to be awarded and receive in the arbitration award or judgment thereon its costs and reasonable

attorney's fees incurred in connection therewith and the enforcement thereof.

/s/	/s/
M. S. Koly	Thomas Redington
Chief Executive Officer	President
Delcath Systems, Inc.	Redington, Inc.
Date	Date

Exhibit A

DELCATH SYSTEMS, INC.
Implementation Schedule
2002-2001 Program Year

FIRST QUARTER

Local/Opportunistic Media
Prepare/Distribute Delcath At A Glance
Stage 6 market road shows
Start Redington outbound contacts
Stage 10-15 fund manager meetings
Stage 2-3 sell-side analyst meetings
Issue corporate milestones

SECOND QUARTER

Stage 6 market road shows
Continue Redington outbound contacts
Evaluate Nova Link conference calls
Stage 2-3 sell-side analyst meetings
Stage 8-12 fund manager meetings
Opportunistic Media
Issue corporate milestones
Review program progress

THIRD QUARTER

Continue Redington outbound contacts
Edit/re-issue Delcath At A Glance
Evaluate NovaLink conference calls
Stage 3 market road shows
Stage 4-6 fund manager meetings
Opportunistic Media
Issue corporate milestones

FOURTH QUARTER

Evaluate NovaLink conference calls
Evaluate additional road shows
Stage 12-18 fund manager meetings
Opportunistic Media
Issue corporate milestones
Discuss/submit Year Two program