

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

FORM 10-KSB

Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2000

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

DEL CATH SYSTEMS, Inc.  
(Exact name of Small Business Issuer as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

06-1245881  
(I.R.S. Employer  
Identification No.)

1100 Summer Street, Stamford, Connecticut  
(Address of principal executive offices)

06905  
(Zip Code)

203-323-8668  
(Issuer's telephone number, 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 -----
Units, each consisting of one share of Common Stock and one redeemable Warrant	Boston Stock Exchange
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:

Units, each consisting of one share of Common Stock and one redeemable Warrant

Common stock, par value \$.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  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 \$3.25 per unit (assuming no value is ascribed to the warrants contained in the units), was \$7,821,947 as of March 20, 2001.

At March 20, 2001, the registrant had outstanding 3,903,852 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:

- o 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.
- o 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 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.
- o 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 1,200,000 Americans will be diagnosed with cancer in 2000. According to the American Cancer Society's "Cancer Facts and Figures -- 2000", 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 Cancer Institute, in the American Cancer Society's "Facts and Figures," estimates the overall costs of cancer to be \$107 billion, including \$37 billion in direct medical costs, \$11 billion for indirect morbidity costs attributable to lost productivity due to illness, and \$59 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 primary liver cancer is estimated to be 1,000,000 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 15,300 new cases of primary liver cancer and 47,700 new cases of malignant melanoma in 2000.

Liver cancer is among the most virulent forms of cancer. In the United States, five-year survival rates are usually less than 10%, 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:

- o Operative risk: limited liver function or poor patient health threatens survival as a result of the surgery; or
- o 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 few 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 micrometastases 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:

- o It is not an option for patients who cannot tolerate an open surgical procedure;
- o 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;
- o It is associated with mortality rates estimated to be between one and five percent; and
- o 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:

- o Infusion catheter -- a thin-walled arterial infusion catheter used to deliver chemotherapy to the liver;
- o Double balloon catheter -- a multi-passageway catheter used to isolate and divert the drug-laden blood exiting the liver;
- o 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;
- o 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
- o 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 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:

- o more chemotherapy agent to the tumor site; and
- o 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:

- o reduction in tumor size; and
- o 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 a new drug application, or a supplemental new drug application, for the chemotherapy agent being administered by the Delcath system. These applications must demonstrate the efficacy 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 which 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 in at least six medical centers and to involve approximately 124 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 second quarter of 2001. As a result, we expect clinical trials to begin during the second quarter of this year. 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 physicians 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 to perform as expected or required, including their failure 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 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.

#### RESEARCH FOR HEPATITIS TREATMENT

Another disease which 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 34 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:

- o oncologists who have primary responsibility for the patient; and
- o 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, instead enlisting the assistance of an interventional radiologist.

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 three 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 materially 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:

- o 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;
- o our ability to educate physicians on the use of the system and its benefits compared to other treatment alternatives; and
- o 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 previously 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 which 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 Burrion OEM division ("Burrion") 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. Burrion has demonstrated that the components it manufactures meet these specifications. Burrion'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 Burrion to manufacture the catheter either for the Phase III 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 Phase III 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.

Delcath competes with all forms of liver cancer treatments which 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 our 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 and a new drug 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 since 1974. 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 which differ from those currently approved, we must obtain approval for revised labeling of a doxorubicin product permitting its use with the Delcath system. This will require the filing of a supplemental or an original new drug application for the administration of doxorubicin through the Delcath system.

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:

- o the refusal of the government to grant approvals;
- o suspension or withdrawal of clearances or approvals;
- o total or partial suspension of production, distribution, sales and marketing;
- o fines;
- o injunctions;
- o civil penalties;
- o recall or seizure of products; and
- o 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 typically 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 "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 biosearch 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 are 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:

- o there are in place design controls, including initial design and design changes;
- o the manufacturing process be regulated, controlled, and documented by the use of written procedures; and
- o 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. We, or 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 doxorubicin does not provide for its delivery with the Delcath system. We must obtain approval of a new drug application for that purpose or partner with the holder of an approved new drug application for doxorubicin to make this change to the labeling of doxorubicin. We are seeking to partner with a drug company for this purpose, but we have no assurance that we will find a partner or that the FDA will approve the application. If this approval is obtained, it would not have a negative effect on the manufacturers of doxorubicin. Rather, they will have the opportunity to expand the use of the drug as a result of changing their label to include the Delcath labeling.

Clinical trials to support the relabeling of doxorubicin to provide for its use with the Delcath system must be conducted in accordance with the FDA's investigational new drug regulations. Phase III clinical trial protocols 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 have identified ten medical centers that have expressed an interest

in conducting the trials. The institutional review boards at two of these medical centers have given their approval to have the clinical trials conducted at their institutions. We are seeking the approval of institutional review boards at additional medical centers by assembling and providing them with information with respect to the trials.

The FDA requires that, in order to obtain approval to relabel 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 a new drug application, or a supplemental new drug application, 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.

If we successfully complete the clinical trials, we believe the manufacturer of doxorubicin will submit to the FDA a new drug application or supplemental new drug application and pre-market approval to deliver doxorubicin 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:

- o complies with the laws of that country;
- o 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
- o 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 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 March 20, 2001, we had seven employees, six of whom were compensated and 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 occupies approximately 3,300 square feet of office space at 1100 Summer Street, Stamford, Connecticut, pursuant to an informal arrangement with the landlord. In addition, the landlord is holding a \$24,000 deposit provided by the Company. We have occupied these facilities since 1992. We believe that we will require additional space in 2001, and are beginning site selection for rental property in the same building or nearby and believe that satisfactory space is available at commercially reasonable rates. 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. The Company currently believes that additional facilities and equipment can be acquired if necessary, although there can be no assurance that additional facilities and equipment will be available upon reasonable or acceptable terms, if at all.

ITEM 3. LEGAL PROCEEDINGS.

The Company is not a party to any litigation.

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

An Action by Consent of Majority Stockholders in Lieu of a Meeting of Common Stockholders was executed as of October 11, 2000, to amend the Company's Amended and Restated Certificate of Incorporation to give effect to a 1-for-1.26661011 reverse stock split of the Common Stock of the Company as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
1,404,013	0	0	0

PART II

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

The Company's units 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 have traded on the Nasdaq SmallCap Market under the symbol "DCTHU" since 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 units. The following table sets forth the per share range of high and low sales prices of our units for the periods indicated:

Unit Price Range	2000	
	High	Low
Quarter ended December 31, 2000 (Since October 19 only)	\$6.344	\$3.313

As of March 20, 2001, there were approximately 90 stockholders of record of our Common Stock and approximately 460 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 generated gross proceeds to the Company of \$7.2 million, of which \$720,000 constituted the underwriting discount. Cash expenses relating to the offering, including the discount and non-accountable expense reimbursement to the underwriter, totaled approximately \$1.8 million. Net proceeds to Delcath were approximately \$5.4 million. From the time of receipt through December 31, 2000, approximately \$385,000 of the net proceeds were expended for working capital. The remaining net proceeds are being held in temporary investments in short-term commercial paper.

## ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR 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 \$572,581 and \$960,185 for the years ended December 31, 1999 and 2000. Cumulative losses from inception through December 31, 2000 were \$12,272,147 plus \$1,498,605 in accrued dividends, of which \$499,535 was paid in cash. 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, 2000, we had approximately \$5,804,000 of cash and cash equivalents. As of that date, our principal commitments consisted of \$798,915 in accounts payable and accrued expenses and \$230,000 in short-term borrowings.

Through December 31, 1999, the Company raised \$9,314,861 through the sale of shares of its Class A Preferred Stock, Class B Preferred Stock and Common Stock.

In April 2000, the Company sold 230,873 shares of Common Stock at \$2.17 per share to existing stockholders in a rights offering yielding proceeds to the Company of \$501,825. In August and September 2000, we also borrowed \$230,000 for which we issued \$230,000 principal amount of promissory notes, which bear interest at an annual rate of 22% and are due 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, our Chairman of the Board and Chief Technology Officer. The Company expects to pay approximately \$267,400 (including interest) to the holders of these notes in May 2001.

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 approximately \$499,535. After underwriting discounts and cash expenses of the offering, the net proceeds to us were approximately \$5.4 million.

Cash used to fund operations from inception through December 31, 2000 was \$8,988,395. Our cash and cash equivalents totaled \$5,803,577 at December 31, 2000.

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

- o phase III clinical trials using doxorubicin with the Delcath system.
- o pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath system for the treatment of liver cancer; and
- o the development of additional products and components.

We expect to begin doxorubicin trials during the second quarter of 2001. These trials 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;

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 \$50,000 in computer, laboratory and testing equipment. We also expect to hire approximately two additional employees in the areas of research and development, regulatory and clinical management, marketing and administrative functions at an estimated annual expense of \$235,000. The number and timing of such hiring will vary depending upon the success of the international marketing efforts and progress of the clinical trials.

We currently anticipate that the net proceeds of our initial public offering, together with our other 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:

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

If the proceeds of our public offering, together with 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 the proceeds of our initial public offering will be sufficient to fund our clinical trials with respect to the use of the Delcath system with doxorubicin 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 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 an 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 above under "Risk Factors That May Effect Results of Operations and Financial Condition" in the Prospectus for our initial public offering in October 2000 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 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, 8-K and 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 very small profit or 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, 2000 of \$4,876,196. 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. If such capital is unavailable either because of general market conditions or the results of the Company's operations, the Company will have to continue to scale back either its investments in new products, or its national supermarket expansion, or both.

#### ITEM 7. FINANCIAL STATEMENTS.

Please refer to pages F-1 through F-14  
Independent Auditors' Report  
Balance Sheet as of December 31, 2000  
Statements of Operations for the years ended December 31, 2000 and 1999 and  
cumulative from inception (August 5, 1988) to December 31, 2000  
Statements of Stockholders' Equity for the years ended December 31, 2000 and  
1999 and cumulative from inception (August 5, 1988) to December 31, 2000  
Statements of Cash Flows for the years ended December 31, 2000 and 1999 and  
cumulative from inception (August 5, 1988) to December 31, 2000  
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 March 20, 2001 are as follows:

Name	Age	Position
M.S. Koly	60	President, Chief Executive Officer and Director
Samuel Herschkowitz, M.D.	51	Chairman and Chief Technology Officer
William I. Bergman	69	Director
James V. Sorrentino, Ph.D.	64	Director
Frank G. Mancuso, Jr.	42	Director

M.S. KOLY has been Chief Executive Officer and Treasurer of Delcath since 1998 and has served as a Director since 1988. 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 Chairman of the Board of Delcath since 1998 and Delcath's Chief Technical Officer since 1991. 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.

WILLIAM I. BERGMAN has been a director of Delcath since 1996. A retired executive, Mr. Bergman was with Richardson-Vicks from 1956 through 1990 most recently as Vice President-controller of North American Operations, vice president-marketing of colds care business and Canadian operations, president and general manager of Vicks health care division, assistant general manager of Vicks International, and executive vice president of Richardson-Vicks Inc. Following the acquisition of Vicks by The Procter & Gamble Company in 1986, he became the president of Richardson-Vicks, U.S.A. and vice president of The Procter & Gamble Company prior to retirement in 1990. He is also a director of ZymeTx, Inc. a biotech company involved in the development of viral diagnostics. His education includes a B.S. from Drexel University and the advanced management program at Harvard University.

JAMES V. SORRENTINO, PH.D. has been a director of Delcath since 1996. Since 1992, Dr. Sorrentino has been President of Healthcare Products Development, Inc., a clinical research organization that designs, organizes and manages clinical trials for the pharmaceutical and biological industry. From 1974 to 1992, he held several research positions with Richardson-Vicks Inc., including director of over-the-counter products, Vice President & director of research and development. After Richardson-Vicks Inc. was acquired by The Procter & Gamble Company, he served as director of worldwide clinical development, non-prescription

drug products of The Procter & Gamble Company. He received an A.B. in Biology, an M.S. in bacteriology, and a Ph.D. in virology/immunology from the Catholic University of America.

FRANK G. MANCUSO, JR., has been a director of Delcath since 1998. Mr. Mancuso has been President of FGM Entertainment since 1985. In the past five years, he has produced numerous movies and television series within his own companies and for Paramount Pictures and MGM/United Artists. He has a B.A. from Upsala College.

#### 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 year ended December 31, 2000, 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.

#### ITEM 10. EXECUTIVE COMPENSATION.

The following table sets forth, for the fiscal years ended December 31, 2000, 1999, and 1998, 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, 2000, 1999, and 1998 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	2000	98,200	0	102,000	0
President	1999	101,250	0	139,746	0
	1998	60,000	0	--	0

#### OPTION GRANTS IN LAST FISCAL YEAR

Stock options were granted to the Named Executive Officers during the 2000 fiscal year as follows:

Name	Number of Shares of Common Stock Underlying Option	Percent of Total Options Granted to Employees in 2000	Exercise Price (\$/Sh.)	Expiration Date
M.S. Koly	60,300	37.2%	3.31	December 2005
M.S. Koly	41,700	25.7%	3.31	December 2005

#### AGGREGATED FISCAL YEAR END OPTION VALUES

Name	Number of Shares of Common Stock Underlying Unexercised Options at December 31, 2000		Value of Unexercised In-the-Money Options at December 31, 2000 (1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
M.S. Koly	40,578	20,289	23,129	11,565
M.S. Koly	25,396	0	14,476	
M.S. Koly	53,483	0	139,056	
M.S. Koly	30,150	30,150	66,029	66,029
M.S. Koly			91,323	

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, 2000, 1999 and 1998 and unexercised options held as of the end of fiscal 2000.

Name	Year	Shares Acquired 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	2000	0	191,307/50,439	334,012/77,539
President	1999	0	119,457/20,289	176,661/11,565
	1998	0		

(1) Calculated based on the fair market value of \$5.50 per share (assuming no value is ascribed to the warrant contained in the unit that trades) at the close of trading on December 29, 2000 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, each non-employee director received a one-time grant in January 1999 of options to purchase 34,505 shares of common stock at a price of \$4.93 per share, all of which are vested. Each non-employee director received a separate one-time grant in December 1999 of options to purchase 22,428 shares of common stock at a price of \$2.90 per share, all of which have vested.

On December 1, 2000, Delcath's Compensation Committee granted options to certain of the directors of Delcath, at an exercise price equal to \$3.3125 per share, the fair market value at the close of trading on November 30, 2000 as reported by The Wall Street Journal (assuming no value is ascribed to the warrant contained in the unit that trades). The options granted to the directors are indicated below:

Name	Incentive Stock Options	Non-Qualified Stock Options
M.S. Koly	60,300(1)	41,700(2)
Samuel Herschkowitz, M.D.	60,300(1)	
William I. Bergman		42,000(2)
James V. Sorrentino, Ph.D.		42,000(2)

(1) One-half vested on December 1, 2000, and one-half vested on January 1, 2001.  
 (2) Vested on December 1, 2000.

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. Our 2000 stock option plan will be submitted for stockholder approval at our next annual meeting. 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, 205,305 shares of common stock for issuance upon exercise of options granted from time to time under the 1992 non-incentive stock option plan and 300,000 shares of common stock for issuance from time to time under the 2000 stock option 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 key employees and employee directors. 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 stock option plan, we may grant incentive or non-qualified options to our officers, employees, directors, consultants, agents and independent contractors. The stock option plans are administered by a committee, currently the stock option and compensation 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, 2000, 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 have been granted to our officers and directors and terminate on the fifth anniversary of their vesting date. We will not grant any additional options under these plans. As of March 20, 2001, we have granted incentive stock options to purchase 120,600 shares of common stock and non-incentive stock options to purchase 127,420 shares of common stock under our 2000 Stock Option Plan, each at a weighted average price of \$3.31. For a period of one year following the effective date of our initial public offering, we will not grant options to our employees, promoters or affiliates which, when added to options previously granted, will exceed 15% of our then outstanding shares of common stock.

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.

#### 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 March 20, 2001, 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	1,666,257	40.2%
Venkol Trust	1,406,773	36.0%
Samuel Herschkowitz, M.D.	343,827	8.5%
Frank G. Mancuso, Jr.	111,840	2.8%
James V. Sorrentino, Ph.D	110,664	2.8%
William I. Bergman	105,834	2.6%
Joseph P. Milana	0	0.0%
All directors and executive officers as a group (six persons) -----	2,142,664	47.1%

M.S. Koly's beneficially owned shares include:

- o 6,007 shares of the 12,014 shares held by Venkol Inc. as nominee for M.S. Koly;
- o 11,731 shares held by M. Ted Koly, M.S. Koly's minor son;
- o 241,746 shares issuable upon exercise of options; and
- o 1,404,013 shares and 2,760 shares issuable upon exercise of warrants held by Venkol Trust.

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

Samuel Herschkowitz's beneficially owned shares include:

- o 6,007 shares of the 12,014 shares held by Venkol Inc. as nominee for Dr. Herschkowitz;
- o 181,253 shares held by Venkol Trust and 356 shares issuable upon the exercise of warrants held by the Venkol Trust, as to which Dr. Herschkowitz has a beneficial remainder interest; and
- o 144,836 shares which are issuable upon exercise of options.

Frank G. Mancuso's beneficially owned shares include:

- o 14,505 shares held by Venkol Trust and 28 shares issuable upon the exercise of warrants held by the Venkol Trust, as to which Mr. Mancuso has a beneficial remainder interest;
- o 56,933 shares issuable upon exercise of options; and
- o 1,424 shares issuable upon exercise of warrants.

James V. Sorrentino's and William I. Bergman's beneficially owned shares include 98,933 shares issuable upon exercise of options.

The number of shares beneficially owned by all directors and executive officers as a group include 1,406,773 shares and 2,760 shares issuable upon exercise of warrants held by Venkol Trust.

#### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

From September 1997 through January 1998, we sold 87,988 shares of common stock to 11 investors for an aggregate consideration to us of \$1,275,000. One of the investors was Johnson & Johnson Development Corporation, which invested \$500,000. As part of that offering, Venkol Ventures, L.P. and Venkol Ventures, Ltd. purchased an aggregate of 20,703 shares of common stock for approximately \$300,000 and Mr. Mancuso, a director of Delcath, purchased 6,901 shares of common stock for \$100,000.

In November 1998, Venkol Ventures, L.P. and Venkol Ventures, Ltd. distributed their shares in Delcath to their limited partners or their designees. The majority of shares were transferred to the Venkol Trust, which is managed

by M.S. Koly, our Chief Executive Officer and a director. The shares transferred to the trust include all of our shares of class A preferred stock, 117,650 shares of our class B preferred stock and 36,076 shares of common stock.

All of our preferred stockholders converted their preferred stock into 833,873 shares of common stock. The preferred stockholders also accepted 687,058 shares of common stock as payment of \$992,780 of estimated accumulated dividends, and a cash dividend of \$496,390 as payment of the balance of the accrued dividend, estimated through September 30, 2000. 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, 612,799 shares of common stock in partial payment of accumulated dividends and a cash dividend of \$221,997 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, 3,494 shares and 20,967 shares of common stock in payment of \$25,825 and \$154,952 of accumulated dividends and cash dividends of approximately \$12,912 and \$77,476, as payment of the balance of the accrued dividends through September 2000.

In June 1999, we sold an aggregate of 46,987 shares of common stock and three-year warrants to purchase an aggregate of 5,218 shares of common stock at \$14.87 per share for aggregate proceeds of \$776,192. Mr. Mancuso made a \$75,000 investment for which he received 4,540 shares of common stock and warrants to purchase 504 shares of common stock.

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 as noted below, the following exhibits were previously filed as an Exhibit to the Company's Registration Statement on Form SB-2 (No. 333-39470) which was declared effective by the Commission on October 19, 2000, and subsequent periodic reports and incorporated herein 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.
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.
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, 2000.

SIGNATURES

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

DELCATH SYSTEMS, Inc.  
Registrant

/s/ M.S. Koly  
-----  
M.S. Koly, President

March 30, 2001  
-----  
Date

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 and Director(Principal Executive Officer)	March 30, 2001
/s/ Joseph P. Milana ----- Joseph P. Milana	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2001
/s/ Samuel Herschkowitz, M.D. ----- Samuel Herschkowitz, M.D.	Chairman of the Board	March 30, 2001
/s/ William I. Bergman ----- William I. Bergman	Director	March 30, 2001
/s/ James V. Sorrentino, Ph.D. ----- James V. Sorrentino, Ph.D.	Director	March 30, 2001
----- Frank G. Mancuso, Jr.	Director	

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, 2000 and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2000 and for the period from August 5, 1988 (inception) to December 31, 2000. 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, 2000 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2000 and for the period August 5, 1988 (inception) to December 31, 2000, in conformity with accounting principles generally accepted in the United States of America.

March 20, 2001  
New York, NY

DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Balance Sheet

ASSETS	DECEMBER 31, 2000
	-----
Current assets:	
Cash and cash equivalents (note 2)	\$ 5,803,577
Interest receivable	32,368
Prepaid insurance	69,166
	-----
Total current assets	5,905,111
Furniture and fixtures, net	5,250
Due from affiliate	24,000
	-----
Total assets	\$ 5,934,361
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	\$ 798,915
Short-term borrowings (note 2)	230,000
	-----
Total current liabilities	1,028,915
	-----
Commitments (note 5)	
Stockholders' equity (note 3):	
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; 3,903,852 shares issued and outstanding	39,039
Additional paid-in capital	18,637,159
Deficit accumulated during development stage	(13,770,752)
	-----
Total stockholders' equity	4,905,446
	-----
Total liabilities and stockholders' equity	\$ 5,934,361
	=====

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, 2000
	1999	2000	
Costs and expenses:			
Legal, consulting and accounting fees	\$ 626,366	470,261	4,987,430
Stock option compensation expense (reversal)	(456,185)	3,800	2,523,970
Compensation and related expenses	200,128	259,446	2,747,616
Other operating expenses	227,817	298,204	2,489,480
	598,126	1,031,711	12,748,496
<b>Total costs and expenses</b>	<b>598,126</b>	<b>1,031,711</b>	<b>12,748,496</b>
<b>Operating loss</b>	<b>(598,126)</b>	<b>(1,031,711)</b>	<b>(12,748,496)</b>
Interest income	43,470	94,555	632,251
Interest expense	(17,925)	(23,029)	(155,902)
	(572,581)	(960,185)	(12,272,147)
<b>Net loss</b>	<b>(572,581)</b>	<b>(960,185)</b>	<b>(12,272,147)</b>
Preferred stock dividends paid in cash	--	(499,535)	=====
	\$ (572,581)	(1,459,720)	=====
<b>Net loss attributable to common stockholders</b>	<b>\$ (572,581)</b>	<b>(1,459,720)</b>	<b>=====</b>
Common share data:			
Basic and diluted loss per share	\$ (0.68)	(0.90)	=====
	838,936	1,621,723	=====
<b>Weighted average number of basic and diluted common stock outstanding</b>	<b>838,936</b>	<b>1,621,723</b>	<b>=====</b>

See accompanying notes to financial statements.





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	--	--	--	--	--	--
Deficit accumulated from inception to December 31, 1998	--	--	--	--	--	--
	--	-----	-----	-----	-----	-----
Balance at December 31, 1998	--	--	2,000,000	20,000	416,675	4,167
Sale of stock, June 30, 1999	--	--	--	--	--	--
Amortization of compensatory stock options granted	--	--	--	--	--	--
Forfeiture of stock options	--	--	--	--	--	--
Shares issued in connection with exercise of warrants	--	--	--	--	--	--
Net loss for year ended 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	--	\$ --	--	\$ --	--	\$ --
	==	=====	=====	=====	=====	=====

Statements of Stockholders' Equity(continued)

Years ended December 31, 2000 and 1999 and cumulative from inception (August 5, 1988) to December 31, 2000

	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
Deficit accumulated from inception to December 31, 1998	--	(10,739,381)	(10,739,381)
	-----	-----	-----
Balance at December 31, 1998	11,422,724	(10,739,381)	715,649
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
Net loss for year ended December 31, 1999	--	(572,581)	(572,581)
	-----	-----	-----
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
	=====	=====	=====

DELICATH SYSTEMS, INC.

(A Development Stage Company)

Statement of Cash Flows

	Years ended December 31,		Cumulative from inception (August 5, 1988) to December 31, 2000
	1999	2000	
Cash flows from operating activities:			
Net loss	\$ (572,581)	(960,185)	(12,272,147)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense (reversal)	(456,185)	--	2,520,171
Stock compensation expense	--	3,800	38,285
Depreciation expense	3,000	3,000	9,750
Amortization of organization costs	--	--	42,165
(Increase) decrease in prepaid expenses	867	(64,999)	(69,166)
(Increase) decrease in interest receivable	1,797	(29,042)	(32,368)
Due from affiliate	--	--	(24,000)
(Decrease) increase in accounts payable and accrued expenses	(69,323)	686,167	798,915
Net cash used in operating activities	(1,092,425)	(361,259)	(8,988,395)
Cash flows from investing activities:			
Purchase of furniture and fixtures	--	--	(15,000)
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	--	--	(57,165)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	801,190	5,873,293	13,413,708
Dividends paid	--	(499,535)	(499,535)
Proceeds from short-term borrowings	--	230,000	1,934,964
Net cash provided by financing activities	801,190	5,603,758	14,849,137
Increase (decrease) in cash and cash equivalents	(291,235)	5,242,499	5,803,577
Cash and cash equivalents at beginning of period	852,313	561,078	--
Cash and cash equivalents at end of period	\$ 561,078	5,803,577	5,803,577
Cash paid for interest	\$ 17,925	23,029	137,977
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

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).

(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 \$9,750 at December 31, 2000.

(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 3(b)).

(f) EARNINGS PER SHARE

Basic earnings per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share reflect the dilutive effect of common stock equivalents using the treasury stock method.

(g) 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, 2000 cash equivalents included commercial paper of \$5,688,551.

(2) SHORT-TERM BORROWINGS

In August and September 2000, the Company borrowed \$230,000 for which the Company issued \$230,000 principal amount of promissory notes, which bear interest at an annual rate of 22% and are due on May 27, 2001. Of these notes, \$50,000 principal amount was to M. S. Koly, Chief Executive Officer, President and a director of Delcath, and \$40,000 principal amount was issued to the mother of Samuel Herschkowitz, the Chairman of the Board and Chief Technology Officer. As of December 31, 2000, interest of approximately \$19,600 is accrued on these notes and approximately \$250,000 of cash was designated for the repayment of these borrowings.

(3) STOCKHOLDERS' EQUITY

The common stock and per share data for all periods gives retroactive effect to a reverse stock split of 1 for 2.2881 shares on September 28, 2000 and 1 for 1.2666 shares on October 11, 2000.

(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, 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 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. 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 will expire 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 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 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 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 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 shares have been granted. A stock option granted 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, the 2000 Stock Option Plan 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, 1999 through December 31, 2000 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, 1998	74,017	\$ 7.56	17,252	\$ 2.90
Granted during 1999	441,664	4.13	17,252	2.90
Canceled during 1999	(34,505)	7.56	--	--
Forfeited during 1999	(39,512)	7.56	--	--
Expired during 1999	--	--	(17,252)	2.90
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

The following summarizes information about shares subject to option at December 31, 2000:

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
189,777	\$ 2.90	\$ 2.90	3.82	189,777	\$ 2.90
248,020	3.31	3.31	5.00	187,720	3.31
269,139	4.93	4.93	3.00	269,139	4.93
706,936	\$2.90 - \$4.93	\$3.82	3.92	646,636	\$4.13

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. In 1999, a former employee of the Company resigned and forfeited all of his non-vested options. As a result, the expense previously accrued for such option grants was reversed. Accordingly, stock option compensation expense/(reversal) associated with the Incentive and Non-Incentive Stock Plans for the years ended December 31, 1999 and 2000 was (\$456,185) and \$3,800, respectively, net of forfeitures of \$554,371 and \$0, 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 for the years ended December 31, 1999 and 2000 would have been increased to the pro forma amounts indicated as follows:

	1999	2000
	-----	-----
Net loss:		
As reported	\$ (572,581)	\$ (960,185)
Pro forma	(944,303)	(1,431,352)
Basic and diluted loss per share		
As reported	\$ (0.68)	\$ (0.90)
Pro forma	(1.12)	(1.13)

The per share weighted average fair value of stock options granted during 1999 and 2000 were \$.92 and \$2.21, 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 1999, respectively: risk free interest rate of 6.5% and 5.5%, and volatility of 76.7% and -0% while no dividend yield and expected lives of five years was assumed for both years.

(4) INCOME TAXES

As of December 31, 2000, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$9,440,000 which are available to offset future federal taxable income, if any, through 2020. The net operating loss carryforwards resulted in a deferred tax asset of approximately \$3,209,000 at December 31, 2000 (\$2,904,000 at December 31, 1999). 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, 2000 and 1999.

(5) PREPAID RENT AND DUE FROM AFFILIATE

The Company occupies office space pursuant to an informal arrangement with its landlord. In addition, the landlord is holding a \$24,000 deposit provided by the Company.

WARRANT AGREEMENT dated as of January 5, 2001 between Delcath Systems, Inc., a Delaware corporation (the "Company"), and Euroland Marketing Solutions, LTD. (hereinafter referred to as the "Consultant").

W I T N E S S E T H:

WHEREAS, the Company proposes to issue to the Consultant warrants (the "Warrants") to purchase up to 150,000 (as such number may be adjusted from time to time pursuant to Article 8 of this Agreement) "Units" (as herewith defined in Article 1 hereof); and

WHEREAS, the Consultant has agreed, pursuant to the Consulting Services Agreement (the "Consulting Services Agreement") dated January 5, 2001 between the Consultant and the Company, to provide, among other services, financial consulting services and advice pertaining to the Company's business in Europe; and

WHEREAS, the Warrants issued pursuant to this Agreement are being issued by the Company to the Consultant or to its designees who are officers and shareholders of the Consultant (collectively, the "Designees"), in consideration for, and as the Consultant's compensation in connection with, the Consulting Services Agreement;

NOW, THEREFORE, in consideration of the premises, the agreements herein set forth and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Grant.  
-----

The Consultant and/or the Designees are hereby granted the right to purchase, at any time from January 5, 2001 until 5:00 P.M., New York City time, on

January 4, 2005 (the "Warrant Exercise Term"), up to 150,000 Units at an initial exercise price (subject to adjustment as provided in Article 8 hereof) of \$7.00 per Unit. Each Unit consists of one fully-paid and non-assessable share (the "Shares") of the Company's Common Stock, \$.01 par value ("Common Stock"), and one Common Stock purchase warrant (the "Unit Warrants"). The Unit Warrants are each exercisable to purchase one fully-paid and non-assessable share of Common Stock at a price of \$6.60 per share (the "Unit Warrant Shares"). The Unit Warrants are exercisable commencing October 19, 2001 (or such earlier date as to which Whale Securities Co., L.P. (the "Underwriter") consents to the Units becoming detachable and separately transferable) (the "Separation Date") until 5:00 P.M., New York City time on October 18, 2005.

2. Warrant Certificates.  
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The warrant certificates delivered and to be delivered pursuant to this Agreement (the "Warrant Certificates") shall be in the form set forth in Exhibit A attached hereto and made a part hereof, with such appropriate insertions, omissions, substitutions and other variations as required or permitted by this Agreement.

3. Exercise of Warrant.  
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The Warrants initially are exercisable at a price of \$7.00 per Unit, payable in cash or by check to the order of the Company, or any combination thereof, subject to adjustment as provided in Article 8 hereof. Upon surrender of the Warrant Certificate with the annexed Form of Election to Purchase duly executed, together with payment of the Exercise Price (as hereinafter defined) for the Units purchased, at the Company's principal offices in Connecticut (currently located at 1100 Summer Street, Stamford, Connecticut 06905) the registered holder of a Warrant Certificate ("Holder" or "Holders")

shall be entitled to receive a certificate or certificates for the Shares so purchased and a certificate or certificates for the Unit Warrants so purchased. The purchase rights represented by each Warrant Certificate are exercisable at the option of the Holder thereof, in whole or in part (but not as to fractional Shares or fractional Unit Warrants). In the case of the purchase of less than all the Units purchasable under any Warrant Certificate, the Company shall cancel said Warrant Certificate upon the surrender thereof and shall execute and deliver a new Warrant Certificate of like tenor for the balance of the Units purchasable thereunder.

4. Issuance of Certificates.  
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Upon the exercise of the Warrants, the issuance of certificates for the Shares purchased and certificates for the Unit Warrants purchased, and upon exercise of the Unit Warrants, the issuance of certificates for the Unit Warrant Shares purchased shall be made forthwith (and in any event within three (3) business days thereafter) without charge to the Holder thereof including, without limitation, any tax which may be payable in respect of the issuance thereof, and such certificates shall (subject to the provisions of Article 5 hereof) be issued in the name of, or in such names as may be directed by, the Holder thereof; provided, however, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any such certificates in a name other than that of the Holder and the Company shall not be required to issue or deliver such certificates unless or until the person or persons requesting the issuance thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid.

The Warrant Certificates and the certificates representing the Shares and the Unit Warrants shall be executed on behalf of the Company by the manual or facsimile signature of the present or any future Chairman or Vice Chairman of the Board of Directors, Chief Executive Officer or President or Vice President of the Company under its corporate seal reproduced thereon, attested to by the manual or facsimile signature of the present or any future Secretary or Assistant Secretary of the Company. Warrant Certificates shall be dated the date of execution by the Company upon initial issuance, division, exchange, substitution or transfer.

Upon exercise, in part or in whole, of the Warrants, certificates representing the Shares and the Unit Warrants purchased, and upon exercise, in whole or in part, of the Unit Warrants, certificates representing the Unit Warrant Shares purchased (collectively, the "Warrant Securities"), shall bear a legend substantially similar to the following:

"The securities represented by this certificate have not been registered for purposes of public distribution under the Securities Act of 1933, as amended (the "Act"), and may not be offered or sold except (i) pursuant to an effective registration statement under the Act, (ii) to the extent applicable, pursuant to Rule 144 under the Act (or any similar rule under such Act relating to the disposition of securities), or (iii) upon the delivery by the holder to the Company of an opinion of counsel, reasonably satisfactory to counsel to the Company, stating that an exemption from registration under such Act is available."

5. Restriction on Transfer of Warrants.

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The Holder of a Warrant Certificate, by the Holder's acceptance thereof, covenants and agrees that the Warrants are being acquired as an investment and not with a view to the distribution thereof, and that the Warrants may not be sold, transferred, assigned, hypothecated or otherwise disposed of, in whole or in part, except to the Designees, unless the Holder provides to the Company a legal opinion, in

form and substance acceptable to the Company, that such sale, transfer, assignment or hypothecation is in full compliance with all applicable U.S. federal and state and foreign securities laws.

6. Price.

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6.1. Initial and Adjusted Exercise Price. The initial exercise price of each Warrant shall be \$7.00 per Unit. The adjusted exercise price shall be the price which shall result from time to time from any and all adjustments of the initial exercise price in accordance with the provisions of Article 8 hereof.

6.2. Exercise Price. The term "Exercise Price" herein shall mean the initial exercise price or the adjusted exercise price, depending upon the context.

7. Registration Rights.

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7.1. Registration Under the Securities Act of 1933. None of the Warrants, Shares, Unit Warrants or Unit Warrant Shares have been registered for purposes of public distribution under the Securities Act of 1933, as amended (the "Act").

7.2. Registrable Securities. As used herein the term "Registrable Security" means each of the Warrants, the Shares, the Unit Warrants, the Unit Warrant Shares and any shares of Common Stock issued upon any stock split or stock dividend in respect of such Shares or Unit Warrant Shares; provided, however, that with respect to any particular Registrable Security, such security shall cease to be a Registrable Security when, as of the date of determination, (i) it has been effectively registered under the Act and disposed of pursuant thereto, (ii) registration under the Act is no longer required for the subsequent public distribution of such security or (iii) it has ceased to be outstanding. The term "Registrable Securities" means any and/or all of

the securities falling within the foregoing definition of a "Registrable Security." In the event of any merger, reorganization, consolidation, recapitalization or other change in corporate structure affecting the Common Stock, such adjustment shall be made in the definition of "Registrable Security" as is appropriate in order to prevent any dilution or enlargement of the rights granted pursuant to this Article 7.

### 7.3. Demand Registration.

(a) At any time during the Warrant Exercise Term, any "Majority Holder" (as such term is defined in Section 7.3(c) below) of the Registrable Securities shall have the right, exercisable by written notice to the Company (the "Demand Registration Request"), to have the Company prepare and file with the Securities and Exchange Commission (the "Commission"), on one occasion, at the sole expense of the Company (except as provided in Section 7.4(b) hereof), a Registration Statement and such other documents, including a prospectus, as may be necessary (in the opinion of both counsel for the Company and counsel for such Majority Holder), in order to comply with the provisions of the Act, so as to permit a public offering and sale of the Registrable Securities by the holders thereof. The Company shall use its best efforts to cause the Registration Statement to become effective under the Act, so as to permit a public offering and sale of the Registrable Securities by the holders thereof. Once effective, the Company will use its best efforts to maintain the effectiveness of the Registration Statement until the earlier of (i) the date that all of the Registrable Securities have been sold or (ii) the date that the holders of the Registrable Securities receive an opinion of counsel to the Company that all of the Registrable Securities may be freely traded (without limitation or restriction as to quantity or timing and without



registration under the Act) under Rule 144(k) promulgated under the Act or otherwise.

(b) The Company covenants and agrees to give written notice of any Demand Registration Request to all holders of the Registrable Securities within ten (10) business days from the date of the Company's receipt of any such Demand Registration Request. After receiving notice from the Company as provided in this Section 7.3(b), holders of Registrable Securities may request the Company to include their Registrable Securities in the Registration Statement to be filed pursuant to Section 7.3(a) hereof by notifying the Company of their decision to have such securities included within ten (10) days of their receipt of the Company's notice.

(c) The term "Majority Holder" as used in Section 7.3 hereof shall mean any holder or any combination of holders of Registrable Securities, if included in such holders' Registrable Securities are that aggregate number of shares of Common Stock (including Shares already issued and Shares issuable pursuant to the exercise of outstanding Warrants, Unit Warrant Shares already issued and Unit Warrant Shares issuable pursuant to the exercise of outstanding Unit Warrants) as would constitute a majority of the aggregate number of Shares (including Shares already issued and Shares issuable pursuant to the exercise of outstanding Warrants, Unit Warrant Shares already issued and Unit Warrant Shares issuable pursuant to the issue of outstanding Unit Warrants) included in all the Registrable Securities.

7.4. Covenants With Respect to Registration. The Company covenants and agrees as follows:

(a) In connection with any registration under Section 7.3 hereof, the Company shall file the Registration Statement as expeditiously as possible, but in

any event no later than forty-five (45) days following receipt of any demand therefor, shall use its best efforts to have any such Registration Statement declared effective at the earliest possible time, and shall furnish each holder of Registrable Securities such number of prospectuses as shall reasonably be requested.

(b) The Company shall pay all costs, fees and expenses (other than underwriting fees, discounts and nonaccountable expense allowance applicable to the Registrable Securities and the fees and expenses of counsel retained by the holders of Registrable Securities) in connection with all Registration Statements filed pursuant to Sections 7.3(a) hereof including, without limitation, the Company's legal and accounting fees, printing expenses, and blue sky fees and expenses.

(c) The Company will take all necessary action which may be required in qualifying or registering the Registrable Securities included in the Registration Statement for offering and sale under the securities or blue sky laws of such states as are reasonably requested by the holders of such securities.

(d) The Company shall indemnify any holder of the Registrable Securities to be sold pursuant to any Registration Statement against all loss, claim, damage, expense or liability (including all expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever), to which such holder may become subject under the Act, the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise, insofar as such losses, claims, damages, expenses, liabilities or actions arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in such Registration Statement except to

the extent that such holder of Registrable Securities is obligated to indemnify the Company pursuant to Section 7.4(e).

(e) Any holder of Registrable Securities to be sold pursuant to a Registration Statement, and such holder's successors and assigns, shall jointly and severally indemnify, the Company, its officers and directors and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, against all loss, claim, damage or expense or liability (including all expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such holder, or such holder's successors or assigns, and included in such Registration Statement.

(f) Promptly after receipt of notice of the commencement of any action in respect of which indemnity may be sought against any indemnifying party under Section 7.4(d) or Section 7.4(e), the indemnified party will notify the indemnifying party in writing of the commencement thereof, and the indemnifying party will, subject to the provisions hereinafter stated, assume the defense of such action (including the employment of counsel selected by the Company and the payment of expenses) insofar as such action relates to an alleged liability in respect of which indemnity may be sought against the indemnifying party. After notice from the indemnifying party of its election to assume the defense of such claim or action, the indemnifying party shall no longer be liable to the indemnified party under Section 7.4(d) or Section 7.4(e), as applicable, for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof other than reasonable costs of investigation;

provided, however, that if, in the reasonable judgment of the indemnified party or parties, it is advisable for the indemnified party or parties to be represented by separate counsel, the indemnified party or parties shall have the right to employ a single counsel to represent the indemnified parties who may be subject to liability arising out of any claim in respect of which indemnity may be sought by the indemnified parties thereof against the indemnifying party, in which event the fees and expenses of such separate counsel shall be borne by the indemnifying party. Any party against whom indemnification may be sought under Sections 7.4(d) or Section 7.5(e) shall not be liable to indemnify any person that might otherwise be indemnified pursuant hereto for any settlement of any action effected without such indemnifying party's consent, which consent shall not be unreasonably withheld.

(g) To provide for just and equitable contribution, if (i) an indemnified party makes a claim for indemnification pursuant to Section 7.4(d) or 7.4(e) hereof (subject to the limitations thereof) and it is finally determined, by a judgment, order or decree not subject to further appeal, that such claim for indemnification may not be enforced, even though this Agreement expressly provides for indemnification in such case; or (ii) any indemnified or indemnifying party seeks contribution under the Act, the Exchange Act, or otherwise, then the Company (including, for this purpose, any contribution made by or on behalf of any director of the Company, any officer of the Company and any controlling person of the Company) as one entity and the Consultant (including, for this purpose, any contribution by or on behalf of each person, if any, who controls the Consultant within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act and each officer, director, shareholder, employee and agent of the

Consultant) as a second entity, shall contribute to the losses, liabilities, claims, damages and expenses whatsoever to which any of them may be subject, based upon considerations such as the relative fault of the Company and the Consultant in connection with the facts which resulted in such losses, liabilities, claims, damages and expenses shall also be considered. The relative fault, in the case of an untrue statement, alleged untrue statement, omission or alleged omission, shall be determined by, among other things, whether such statement, alleged statement, omission or alleged omission relates to information supplied by the Company or by the Consultant, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement, alleged statement, omission or alleged omission. The Company and the Consultant agree that it would be unjust and inequitable if the respective obligations of the Company and the Consultant for contribution were determined by pro rata or per capita allocation of the aggregate losses, liabilities, claims, damages and expenses or by any other method of allocation that does not reflect the equitable considerations referred to in this Section 7.4(g). No person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) will be entitled to contribution from any person who is not guilty of such fraudulent misrepresentation. For purposes of this Section 7.4(g), each person, if any, who controls the Consultant within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act and each officer, director, shareholder, employee and agent of the Consultant will have the same rights to contribution as the Consultant, and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20(a) of the Exchange Act, each officer of the Company and each director of the

Company will have the same rights to contribution as the Company, subject in each case to the provisions of this Section 7.4(g). Anything in this Section 7.4(g) to the contrary notwithstanding, no party will be liable for contribution with respect to the settlement of any claim or action effected without its written consent. This Section 7.4(g) is intended to supersede, to the extent permitted by law, any right to contribution under the Act or the Exchange Act or otherwise available.

(h) Nothing contained in this Agreement shall be construed as requiring any Holder to exercise the Warrants or the Unit Warrants included in the Units underlying such Warrants prior to the initial filing of any Registration Statement or the effectiveness thereof.

(i) The Company shall promptly deliver copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the Registration Statement to each holder of Registrable Securities included for such registration in such Registration Statement pursuant to Section 7.3 hereof requesting such correspondence and memoranda and to the managing underwriter, if any, of the offering in connection with which such holder's Registrable Securities are being registered and shall permit each holder of Registrable Securities and such underwriter to do such reasonable investigation, upon reasonable advance notice, with respect to information contained in or omitted from the Registration Statement as it deems reasonably necessary to comply with applicable securities laws or rules of the National Association of Securities Dealers, Inc. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with

its officers and independent auditors, all to such reasonable extent and at such reasonable times and as often as any such holder of Registrable Securities or underwriter shall reasonably request.

8. Adjustments of Exercise Price and Number of Units.  
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8.1. Computation of Adjusted Price. In case the Company shall at any time after the date hereof pay a dividend in shares of Common Stock or make a distribution in shares of Common Stock, then upon such dividend or distribution the Exercise Price in effect immediately prior to such dividend or distribution shall forthwith be reduced to a price determined by dividing:

(a) an amount equal to the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution multiplied by the Exercise Price in effect immediately prior to such dividend or distribution, by

(b) the total number of shares of Common Stock outstanding immediately after such issuance or sale. For the purposes of any computation to be made in accordance with the provisions of this Section 8.1, the Common Stock issuable by way of dividend or other distribution on any stock of the Company shall be deemed to have been issued immediately after the opening of business on the date following the date fixed for the determination of stockholders entitled to receive such dividend or other distribution.

8.2. Subdivision and Combination. In case the Company shall at any time subdivide or combine the outstanding shares of Common Stock, the Exercise Price shall forthwith be proportionately decreased in the case of subdivision or increased in the case of combination.

8.3. Adjustment in Number of Units. Upon each adjustment of the Exercise Price pursuant to the provisions of this Article 8, the number of Units issuable upon the exercise of each Warrant shall be adjusted to the nearest full number of Units by multiplying a number equal to the Exercise Price in effect immediately prior to such adjustment by the number of Units issuable upon exercise of the Warrants immediately prior to such adjustment and dividing the product so obtained by the adjusted Exercise Price.

8.4. Reclassification, Consolidation, Merger, etc. In case of any reclassification or change of the outstanding shares of Common Stock (other than a change in par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), or in the case of any consolidation of the Company with, or merger of the Company into, another corporation (other than a consolidation or merger in which the Company is the surviving corporation and which does not result in any reclassification or change of the outstanding shares of Common Stock, except a change as a result of a subdivision or combination of such shares or a change in par value, as aforesaid), or in the case of a sale or conveyance to another corporation of the property of the Company as an entirety, the Holders shall thereafter have the right to purchase the kind and number of shares of stock and other securities and property receivable upon such reclassification, change, consolidation, merger, sale or conveyance as if the Holders were the owners of the shares of Common Stock underlying the Warrants and the Unit Warrant Shares contained in the Unit Warrants underlying such Warrants immediately prior to any such events at a price equal to the product of (x) the number of shares of Common Stock issuable upon exercise of the Warrants and the Unit Warrants



underlying such Warrants and (y) the Exercise Price in effect immediately prior to the record date for such reclassification, change, consolidation, merger, sale or conveyance as if such Holders had exercised the Warrants and the Unit Warrants underlying such Warrants.

8.5. Adjustment of Unit Warrants Exercise Price and Securities on Exercise of Unit Warrant. With respect to any of the Unit Warrants underlying the Warrants, whether or not the Warrants have been exercised and whether or not the Warrants are issued and outstanding, the exercise price for, and the number of, shares of Common Stock issuable upon exercise of the Unit Warrants shall be automatically adjusted in accordance with Section 9 of the Unit Warrant Agreement, upon the occurrence of any of the events described therein. Thereafter, the underlying Unit Warrants shall be exercisable at such adjusted exercise price and for such adjustment number of underlying shares of Common Stock.

8.6. Determination of Outstanding Shares of Common Stock. The number of shares of Common Stock at any one time outstanding shall include the aggregate number of shares of Common Stock issued and the aggregate number of shares of Common Stock issuable upon the exercise of options, rights, warrants and upon the conversion or exchange of convertible or exchangeable securities.

8.7. Dividends and Other Distributions with Respect to Outstanding Securities. In the event that the Company shall at any time prior to the exercise of all Warrants make any distribution of its assets to holders of its Common Stock as a liquidating or a partial liquidating dividend, then the holder of Warrants who exercises its Warrants after the record date for the determination of those holders of Common Stock

entitled to such distribution of assets as a liquidating or partial liquidating dividend shall be entitled to receive for the Warrant Price per Warrant, in addition to each share of Common Stock, the amount of such distribution (or, at the option of the Company, a sum equal to the value of any such assets at the time of such distribution as determined by the Board of Directors of the Company in good faith) which would have been payable to such holder had he been the holder of record of the Common Stock receivable upon exercise of his Warrant on the record date for the determination of those entitled to such distribution. At the time of any such dividend or distribution, the Company shall make appropriate reserves to ensure the timely performance of the provisions of this Section 8.7.

8.8. Subscription Rights for Shares of Common Stock or Other Securities. In the case that the Company or an affiliate of the Company shall at any time after the date hereof and prior to the exercise of all the Warrants issue any rights, warrants or options to subscribe for shares of Common Stock or any other securities of the Company or of such affiliate to all the stockholders of the Company, the Holders of unexercised Warrants on the record date set by the Company or such affiliate in connection with such issuance of rights, warrants or options shall be entitled, in addition to the shares of Common Stock or other securities receivable upon the exercise of the Warrants, to receive such rights, warrants or options that such Holders would have been entitled to receive had they been, on such record date, the holders of record of the number of whole shares of Common Stock then issuable upon exercise of their outstanding Warrants (assuming for purposes of this Section 8.8), that the exercise of the Warrants is permissible immediately upon issuance).

9. Exchange and Replacement of Warrant Certificates.

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Each Warrant Certificate is exchangeable without expense, upon the surrender thereof by the registered Holder at the principal executive office of the Company, for a new Warrant Certificate of like tenor and date representing in the aggregate the right to purchase the same number of securities in such denominations as shall be designated by the Holder thereof at the time of such surrender.

Upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of any Warrant Certificate, and, in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it, and reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of the Warrant Certificate, if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor, in lieu thereof.

10. Elimination of Fractional Interests.

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The Company shall not be required to issue certificates representing fractions of Units, nor shall it be required to issue scrip or pay cash in lieu of fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up to the nearest whole number of Shares and Unit Warrants.

11. Reservation and Listing of Securities.

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The Company shall at all times reserve and keep available out of its authorized shares of Common Stock, solely for the purpose of issuance upon the exercise of the Warrants and the Unit Warrants, such number of shares of Common Stock as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Warrants and payment of the Exercise Price therefor,

all Shares issuable upon such exercise shall be duly and validly issued, fully paid, non-assessable and not subject to the preemptive rights of any stockholder. The Company further covenants and agrees that upon exercise of the Unit Warrants underlying the Warrants and payment of the Unit Warrant exercise price therefor, all Unit Warrant Shares issuable upon such exercise shall be duly and validly issued, fully paid, non-assessable and not subject to the preemptive rights of any stockholder.

12. Notices to Warrant Holders.

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Nothing contained in this Agreement shall be construed as conferring upon the Holder or Holders the right to vote or to consent or to receive notice as a stockholder in respect of any meetings of stockholders for the election of directors or any other matter, or as having any rights whatsoever as a stockholder of the Company. If, however, at any time prior to the expiration of the Warrants and their exercise, any of the following events shall occur:

(a) the Company shall take a record of the holders of its shares of Common Stock for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of current or retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company; or

(b) the Company shall offer to all the holders of its Common Stock any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor; or

(c) a dissolution, liquidation or winding up of the Company (other than in connection with a consolidation or merger) or a sale of all or substantially all of its property, assets and business as an entirety shall be proposed; or

(d) reclassification or change of the outstanding shares of Common Stock (other than a change in par value to no par value, or from no par value to par value, or as a result of a subdivision or combination), consolidation of the Company with, or merger of the Company into, another corporation (other than a consolidation or merger in which the Company is the surviving corporation and which does not result in any reclassification or change of the outstanding shares of Common Stock, except a change as a result of a subdivision or combination of such shares or a change in par value, as aforesaid), or a sale or conveyance to another corporation of the property of the Company as an entirety is proposed; or

(e) The Company or an affiliate of the Company shall propose to issue any rights to subscribe for shares of Common Stock or any other securities of the Company or of such affiliate to all the shareholders of the Company; then, in any one or more of said events, the Company shall give written notice to the Holder or Holders of such event at least fifteen (15) days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the stockholders entitled to such dividend, distribution, convertible or exchangeable securities or subscription rights, options or warrants, or entitled to vote on such proposed dissolution, liquidation, winding up or sale. Such notice shall specify such record date or the date of closing the transfer books, as the case may be. Failure to give such notice or any defect therein shall not affect the validity of any action taken in

connection with the declaration or payment of any such dividend or distribution, or the issuance of any convertible or exchangeable securities or subscription rights, options or warrants, or any proposed dissolution, liquidation, winding up or sale.

13. Unit Warrants  
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The form of the certificates representing the Unit Warrants (and the form of election to purchase shares of Common Stock upon the exercise of the Unit Warrants and the form of assignment printed on the reverse thereof) shall be substantially as set forth in Exhibit "A" to the Unit Warrant Agreement; provided, however, (i) each Unit Warrant issuable upon exercise of the Warrants shall evidence the right to initially purchase one fully paid and non-assessable share of Common Stock in respect of the Unit Warrant at an initial purchase price of \$6.60 per share from the Separation Date until 5:00 p.m. on October 18, 2005 and (ii) the Target Redemption Price (as defined in the Public Warrant Agreement) of the Unit Warrants is 150% of the then effective exercise price of the Unit Warrants. As set forth in Section 8.5 of this Agreement, the exercise price of the Unit Warrants and the number of shares of Common Stock issuable upon the exercise of the Unit Warrants are subject to adjustment, whether or not the Warrants have been exercised and the Unit Warrants have been issued, in the manner and upon the occurrence of the events set forth in Section 9 of the Unit Warrant Agreement, which is hereby incorporated herein by reference and made a part hereof as is set forth in its entirety herein. Subject to the provisions of this Agreement and upon issuance of the Unit Warrants underlying the Warrants, each registered holder of such Unit Warrants shall have the right to purchase from the Company (and the Company shall issue to such registered holders) up to the number of fully paid and

non-assessable shares of Common Stock underlying such Unit Warrants (subject to adjustment as provided herein and in the Unit Warrant Agreement), free and clear of all preemptive rights of shareholders, provided that such registered holder complies with the terms governing exercise of the Unit Warrants set forth in the Unit Warrant Agreement, and pays the applicable exercise price, determined in accordance with the terms of the Unit Warrant Agreement. Upon exercise of the Unit Warrants, the Company shall forthwith issue to the registered holder of any such Unit Warrant in his name or in such name as may be directed by him, certificates for the number of shares of Common Stock and the number of Unit Warrants so purchased. Except as otherwise provided in Section 8.5 hereof, the Unit Warrants underlying the Warrants shall be governed in all respects by the terms of the Unit Warrant Agreement. The Unit Warrants shall be transferable in the manner provided in the Unit Warrant Agreement, and upon any such transfer, a new Unit Warrant shall be issued promptly to the transferee. The Company will send to each Holder, irrespective of whether or not the warrants have been exercised, any and all notices required by the Unit Warrant Agreement to be sent to holders of the Unit Warrants.

14. Notices.

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All notices, requests, consents and other communications hereunder shall be in writing and shall be deemed to have been duly made when delivered, or mailed by registered or certified mail, return receipt requested:

- (a) If to a registered Holder of the Warrants, to the address of such Holder as shown on the books of the Company; or
- (b) If to the Company, to the address set forth in Section 3 of

this Agreement or to such other address as the Company may designate by notice to the Holders.

15. Supplements and Amendments.  
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The Company and the Consultant may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates and/or Warrant Securities in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any provisions herein, or to make any other provisions in regard to matters or questions arising hereunder which the Company and the Consultant may deem necessary or desirable and which the Company and the Consultant deem not to adversely affect the interests of the Holders of Warrant Certificates and/or Warrant Securities.

16. Successors.  
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All the covenants and provisions of this Agreement by or for the benefit of the Company and the Holders inure to the benefit of their respective successors and assigns hereunder.

17. Termination.  
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This Agreement shall terminate at the close of business on January 4, 2005. Notwithstanding the foregoing, this Agreement will terminate on any earlier date when all Warrants and Unit Warrants have been exercised and all Warrant Securities have been resold to the public; provided, however, that the provisions of Section 7.4(d) and Section 7.4(e) shall survive any termination pursuant to this Section 17 until the close of business on January 4, 2008.



18. Governing Law.

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This Agreement and each Warrant Certificate issued hereunder shall be deemed to be a contract made under the laws of the State of Connecticut and for all purposes shall be construed in accordance with the laws of said State.

19. Benefits of This Agreement.

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Nothing in this Agreement shall be construed to give to any person or corporation other than the Company and the Consultant and any other registered holder or holders of the Warrant Certificates or Warrant Securities any legal or equitable right, remedy or claim under this Agreement; and this Agreement shall be for the sole and exclusive benefit of the Company and the Consultant and any other holder or holders of the Warrant Certificates or Warrant Securities.

20. Counterparts.

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This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and such counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

EUROLAND MARKETING SOLUTIONS, LTD.

DELCATH SYSTEMS, INC.

By: /s/ Y. Gorobets  
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Name: Y. Gorobets  
Title: Director  
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By: /s/ M.S. Koly  
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M.S. Koly  
Title: Chief Executive Officer

EXHIBIT A

THE WARRANTS REPRESENTED BY THIS CERTIFICATE AND THE OTHER SECURITIES ISSUABLE UPON EXERCISE THEREOF HAVE NOT BEEN REGISTERED FOR PURPOSES OF PUBLIC DISTRIBUTION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND MAY NOT BE OFFERED OR SOLD EXCEPT (i) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT, (ii) TO THE EXTENT APPLICABLE, PURSUANT TO RULE 144 UNDER SUCH ACT (OR ANY SIMILAR RULE UNDER SUCH ACT RELATING TO THE DISPOSITION OF SECURITIES), OR (iii) UPON THE DELIVERY BY THE HOLDER TO THE COMPANY OF AN OPINION OF COUNSEL, REASONABLY SATISFACTORY TO COUNSEL FOR THE COMPANY, STATING THAT AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT IS AVAILABLE.

THE TRANSFER OR EXCHANGE OF THE WARRANTS REPRESENTED BY THIS CERTIFICATE IS RESTRICTED IN ACCORDANCE WITH THE WARRANT AGREEMENT REFERRED TO HEREIN.

EXERCISABLE ON OR BEFORE  
5:00 P.M., NEW YORK CITY TIME, January 4, 2005

No. W-2

150,000 Warrants

WARRANT CERTIFICATE

This Warrant Certificate certifies that Euroland Marketing Solutions, LTD. or registered assigns, is the registered holder of (150,000) Warrants to purchase, at any time from January 5, 2001 until 5:00 P.M. New York City time on January 4, 2005 ("Expiration Date"), up to 150,000 units ("Units"), each consisting of one fully-paid and non-assessable share of common stock, par value \$.01 per share (the "Common Stock"), of Delcath Systems, Inc., a Delaware corporation (the "Company"), and one Common Stock Purchase Warrant, each Common Stock Purchase Warrant entitling the holder thereof to purchase one share of Common Stock (collectively, the "Unit Warrants") at the initial exercise price, subject to adjustment in certain events (the "Exercise Price"), of \$7.00 per Unit upon surrender of this Warrant Certificate and payment of the Exercise Price at an office or agency of the Company, but subject to the conditions set forth herein and in the Warrant Agreement dated as of January 5, 2001 between the Company and Euroland Marketing Solutions, LTD. (the "Warrant Agreement"). Payment of the Exercise Price may be made in cash, or by certified or official bank check in New York Clearing House funds payable to the order of the Company, or any combination thereof.

Each Unit Warrant issuable upon the exercise of a Warrant is initially exercisable from the Separation Date through January 4, 2005, for one fully-paid and non-assessable share of Common Stock at an initial exercise price of \$6.60 per share. The Unit Warrants are issuable pursuant to the terms and provisions of a certain agreement dated as of October 24, 2000 by and among the Company, Whale Securities Co., L.P. (the "Underwriter") and American Stock Transfer & Trust Company (the "Unit Warrant Agreement"). The Unit Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to (except as otherwise provided in the Warrant Agreement) for a description of the rights, limitations of rights, manner of exercise, anti-dilution provisions and other provisions with respect to the Unit Warrants.

No Warrant may be exercised after 5:00 P.M., New York City time, on the Expiration Date, at which time all Warrants evidenced hereby, unless exercised prior thereto, shall thereafter be void.

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants issued pursuant to the Warrant Agreement, which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Company and the holders (the words "holders" or "holder" meaning the registered holders or registered holder) of the Warrants.

The Warrant Agreement provides that upon the occurrence of certain events, the Exercise Price and the type and/or number of the Company's securities issuable thereupon may, subject to certain conditions, be adjusted. In such event, the Company will, at the request of the holder, issue a new Warrant Certificate evidencing the adjustment in the Exercise Price and the number and/or type of securities issuable upon the exercise of the Warrants; provided, however, that the failure of the Company to issue such new Warrant Certificates shall not in any way change, alter, or otherwise impair, the rights of the holder as set forth in the Warrant Agreement.

Upon due presentment for registration of transfer of this Warrant Certificate at an office or agency of the Company, a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided herein and in the Warrant Agreement, without any charge except for any tax, or other governmental charge imposed in connection therewith.

Upon the exercise of less than all of the Warrants evidenced by this Certificate, the Company shall forthwith issue to the holder hereof a new Warrant Certificate representing such number of unexercised Warrants.

The Company may deem and treat the registered holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, and of

any distribution to the holder(s) hereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary.

All terms used in this Warrant Certificate which are defined in the Warrant Agreement shall have the meanings assigned to them in the Warrant Agreement.

IN WITNESS WHEREOF, the Company has caused this Warrant Certificate to be duly executed under its corporate seal.

Dated: January 5, 2001

DELCATH SYSTEMS, INC.

By: -----  
M.S. Koly  
Title: Chief Executive Officer

[FORM OF ELECTION TO PURCHASE]

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to purchase \_\_\_\_\_ Units and herewith tenders in payment for such securities cash or a certified or official bank check payable in New York Clearing House Funds to the order of Delcath Systems, Inc. in the amount of \$ \_\_\_\_\_, all in accordance with the terms hereof. The undersigned requests that a certificate for such securities be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_, and that such Certificate be delivered to \_\_\_\_\_, whose address is \_\_\_\_\_.

Dated: \_\_\_\_\_ Signature: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

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-----

(Insert Social Security or Other Identifying Number of Holder)

[FORM OF ASSIGNMENT]

(To be executed by the registered holder if such holder desires to transfer the Warrant Certificate.)

FOR VALUE RECEIVED

-----  
hereby sells, assigns and transfers unto -----

-----  
(Please print name and address of transferee)

this Warrant Certificate, together with all right, title and interest therein, and does hereby irrevocably constitute and appoint \_\_\_\_\_, Attorney, to transfer the within Warrant Certificate on the books of the within-named Company, with full power of substitution.

Dated: \_\_\_\_\_ Signature: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

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(Insert Social Security or Other Identifying Number of Holder)

THE WARRANTS REPRESENTED BY THIS CERTIFICATE AND THE OTHER SECURITIES ISSUABLE UPON EXERCISE THEREOF HAVE NOT BEEN REGISTERED FOR PURPOSES OF PUBLIC DISTRIBUTION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND MAY NOT BE OFFERED OR SOLD EXCEPT (i) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT, (ii) TO THE EXTENT APPLICABLE, PURSUANT TO RULE 144 UNDER SUCH ACT (OR ANY SIMILAR RULE UNDER SUCH ACT RELATING TO THE DISPOSITION OF SECURITIES), OR (iii) UPON THE DELIVERY BY THE HOLDER TO THE COMPANY OF AN OPINION OF COUNSEL, REASONABLY SATISFACTORY TO COUNSEL FOR THE COMPANY, STATING THAT AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT IS AVAILABLE.

THE TRANSFER OR EXCHANGE OF THE WARRANTS REPRESENTED BY THIS CERTIFICATE IS RESTRICTED IN ACCORDANCE WITH THE WARRANT AGREEMENT REFERRED TO HEREIN.

EXERCISABLE ON OR BEFORE  
5:00 P.M., NEW YORK CITY TIME, January 4, 2005

No. W-2

150,000 Warrants

WARRANT CERTIFICATE

This Warrant Certificate certifies that Euroland Marketing Solutions, LTD. or registered assigns, is the registered holder of (150,000) Warrants to purchase, at any time from January 5, 2001 until 5:00 P.M. New York City time on January 4, 2005 ("Expiration Date"), up to 150,000 units ("Units"), each consisting of one fully-paid and non-assessable share of common stock, par value \$.01 per share (the "Common Stock"), of Delcath Systems, Inc., a Delaware corporation (the "Company"), and one Common Stock Purchase Warrant, each Common Stock Purchase Warrant entitling the holder thereof to purchase one share of Common Stock (collectively, the "Unit Warrants") at the initial exercise price, subject to adjustment in certain events (the "Exercise Price"), of \$7.00 per Unit upon surrender of this Warrant Certificate and payment of the Exercise Price at an office or agency of the Company, but subject to the conditions set forth herein and in the Warrant Agreement dated as of January 5, 2001 between the Company and Euroland Marketing Solutions, LTD. (the "Warrant Agreement"). Payment of the Exercise Price may be made in cash, or by certified or official bank check in New York Clearing House funds payable to the order of the Company, or any combination thereof.

Each Unit Warrant issuable upon the exercise of a Warrant is initially exercisable from the Separation Date through January 4, 2005, for one fully-paid and non-assessable share of Common Stock at an initial exercise price of \$6.60 per share. The Unit Warrants are issuable pursuant to the terms and provisions of a certain agreement dated as of October 24, 2000 by and among the Company, Whale Securities Co., L.P. (the "Underwriter") and American Stock Transfer & Trust Company (the "Unit Warrant Agreement"). The Unit Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to (except as otherwise provided in the Warrant Agreement) for a description of the rights, limitations of rights, manner of exercise, anti-dilution provisions and other provisions with respect to the Unit Warrants.

No Warrant may be exercised after 5:00 P.M., New York City time, on the Expiration Date, at which time all Warrants evidenced hereby, unless exercised prior thereto, shall thereafter be void.

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants issued pursuant to the Warrant Agreement, which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Company and the holders (the words "holders" or "holder" meaning the registered holders or registered holder) of the Warrants.

The Warrant Agreement provides that upon the occurrence of certain events, the Exercise Price and the type and/or number of the Company's securities issuable thereupon may, subject to certain conditions, be adjusted. In such event, the Company will, at the request of the holder, issue a new Warrant Certificate evidencing the adjustment in the Exercise Price and the number and/or type of securities issuable upon the exercise of the Warrants; provided, however, that the failure of the Company to issue such new Warrant Certificates shall not in any way change, alter, or otherwise impair, the rights of the holder as set forth in the Warrant Agreement.

Upon due presentment for registration of transfer of this Warrant Certificate at an office or agency of the Company, a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided herein and in the Warrant Agreement, without any charge except for any tax, or other governmental charge imposed in connection therewith.

Upon the exercise of less than all of the Warrants evidenced by this Certificate, the Company shall forthwith issue to the holder hereof a new Warrant Certificate representing such number of unexercised Warrants.

The Company may deem and treat the registered holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of

ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, and of



any distribution to the holder(s) hereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary.

All terms used in this Warrant Certificate which are defined in the Warrant Agreement shall have the meanings assigned to them in the Warrant Agreement.

IN WITNESS WHEREOF, the Company has caused this Warrant Certificate to be duly executed under its corporate seal.

Dated: January 5, 2001

DELCATH SYSTEMS, INC.

By: /s/ M.S. Koly

-----  
M.S. Koly

Title: Chief Executive Officer

[FORM OF ELECTION TO PURCHASE]

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to purchase \_\_\_\_\_ Units and herewith tenders in payment for such securities cash or a certified or official bank check payable in New York Clearing House Funds to the order of Delcath Systems, Inc. in the amount of \$ \_\_\_\_\_, all in accordance with the terms hereof. The undersigned requests that a certificate for such securities be registered in the name of \_\_\_\_\_, whose address is \_\_\_\_\_, and that such Certificate be delivered to \_\_\_\_\_, whose address is \_\_\_\_\_.

Dated: \_\_\_\_\_ Signature: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

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(Insert Social Security or Other Identifying Number of Holder)

[FORM OF ASSIGNMENT]

(To be executed by the registered holder if such holder desires to transfer the Warrant Certificate.)

FOR VALUE RECEIVED

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hereby sells, assigns and transfers unto

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(Please print name and address of transferee)

this Warrant Certificate, together with all right, title and interest therein, and does hereby irrevocably constitute and appoint \_\_\_\_\_, Attorney, to transfer the within Warrant Certificate on the books of the within-named Company, with full power of substitution.

Dated: \_\_\_\_\_ Signature: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

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-----  
(Insert Social Security or Other Identifying Number of Holder)

## CONSULTING SERVICES AGREEMENT

This CONSULTING SERVICES AGREEMENT (the "Agreement") is made as of this 5th day of January, 2001, between DELCATH SYSTEMS, INC., a Delaware corporation (the "Company"), and EUROLAND MARKETING SOLUTIONS, LTD., a company organized under the laws of British Virgin Islands with an address of 23 Rue Aldringen, L1118 Luxembourg (the "Consultant"). Consultant has been retained by Company to serve as a consultant and advisor, on a non-exclusive basis for a period of 1 year, on the following terms and conditions:

## SERVICES

Consultant will provide the following services to Company:

- a. Financial consulting services and advice pertaining to the Company's business in Europe, as the Company may from time to time reasonably request.
- b. Consultant will assist the Company in identifying strategic opportunities in Europe.
- c. Consultant will use its best efforts, to arrange introductions and meetings between representatives of the Company and individuals and financial institutions in the investment community in Europe.

## COMPENSATION

Company agrees to issue on January 5, 2001, and Consultant agrees to accept, a Warrant to purchase up to One Hundred Fifty Thousand (150,000) Units of the Delcath Systems, Inc., at an exercise price equal to \$7.00 per Unit (the "Warrant"). The Units underlying the Warrant are identical to the Units offered by the Company in initial public offering on October 19, 2000 except that they have not been registered under the Securities Act of 1933. The Warrant is fully vested on grant and may be exercised at any time, in whole or in part, during the three-year period commencing on the date of issuance. The Company grants to Consultant a one-time demand registration right such that the Company agrees that, upon the request of Consultant, it will, at its own expense (except for underwriting fees, discounts and nonaccountable expense allowances and the fees of counsel to the holders of the registrable securities), register the Units underlying the Warrant or

the shares and warrants included in the Warrant in case they trade separately. This demand registration right shall expire three years from the date of this Agreement.

## GENERAL PROVISIONS

- a. This Agreement supersedes any and all agreements, either oral or written, between the parties hereto with respect to the provisions of Services by Consultant for Company and contains all the covenants and agreements between the parties with respect to the rendering of such services in any manner whatsoever.
- b. Any modifications of this Agreement will be effective only if in writing and signed by both parties.
- c. If any part of the Agreement is found to be illegal or invalid by a legal authority that shall not affect the remainder of the Agreement, which should remain in full force and effect.
- d. Consultant represents and warrants to the Company that this Agreement and the activities of Consultant contemplated by this Agreement are in compliance with all applicable securities laws of the United States and Luxembourg. Consultant will protect, defend and indemnify the Company from, and hold it harmless against, all liability, losses, damages, costs or expenses that the Company may at any time suffer, incur or be required to pay by reason of the violation of the securities laws of the United States, Luxembourg or any other country, or any political subdivision thereof, as a result of entering into this Agreement or the activities contemplated under it.
- e. This Agreement shall be governed by the laws of the State of Delaware, U.S.A. The parties for themselves, and their permitted successors and assigns, hereby irrevocably submit to the jurisdiction of the federal and state courts in the State of Delaware for the resolution of any disputes arising under this Agreement.

AGREED TO AND ACCEPTED ON THE DATE FIRST WRITTEN ABOVE.

DELCATH SYSTEMS, INC.

CONSULTANT

BY: /s/ M.S. Koly

BY: /s/ Y. Gorobets

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M.S. KOLY, PRESIDENT AND CEO

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Y. GOROBETS, DIRECTOR