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

FORM 10-K

x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2012

o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission file number: 001-16133

DELCATH SYSTEMS, INC.

Delaware	**06-1245881**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
810 Seventh Avenue, 35th Floor, New York, NY	**10019**
(Address of principal executive offices)	(Zip Code)

212-489-2100
(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None.

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

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o — Accelerated filer x
Non-accelerated filer o (Do not check if smaller reporting company) — Smaller reporting company o

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

Yes o No x

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based on the closing sale price on The NASDAQ Capital Market of $1.65 per share, was $106,054,648 as of June 30, 2012.

At March 11, 2013, the registrant had outstanding 91,173,443 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2013 Annual Meeting of Stockholders are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K. The definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business.	1
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	30
Item 2.	Properties	30
Item 3.	Legal Proceedings	30
Item 4.	Removed and Reserved	30
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	31
Item 6.	Selected Financial Data	33
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A.	Quantitative and Qualitative Disclosure About Market Risk	37
Item 8.	Consolidated Financial Statements and Supplementary Data	39
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	40
Item 9A.	Controls and Procedures	40
Item 9B.	Other Information	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits and Consolidated Financial Statement Schedules	43
	SIGNATURES	44

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the period ended December 31, 2012 contains certain “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as “anticipates,” “expects,” “intends,” “plans,” “predicts,” “believes,” “seeks,” “estimates,” “could,” “would,” “will,” “may,” “can,” “continue,” “potential,” “should,” and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2012 that are not historical facts are hereby identified as “forward-looking statements” for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2012 in Item 1A under “Risk Factors” as well as in Item 7A “Quantitative and Qualitative Disclosures About Market Risk,” our Quarterly Report on Form 10-Q for the period ended September 30, 2012 in Part II, Item 1A under “Risk Factors” as well as in Part I, Item 3 “Quantitative and Qualitative Disclosures About Market Risk” and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the progress and results of our research and development programs;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture the CHEMOSAT/Melblez Kit system; and
- our ability to successfully commercialize the CHEMOSAT/Melblez Kit system and successfully obtain reimbursement; and
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the “Company”, “Delcath”, “Delcath Systems”, “we”, “our”, and “us” refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 810 Seventh Avenue, 35th Floor, New York, New York 10019. Our telephone number is (212) 489-2100.

Company Overview

We are a specialty pharmaceutical and medical device company focused on oncology. Our proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our initial focus is on the treatment of primary and metastatic liver cancers. We believe that the proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, we announced that our randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. We have also completed a multi-arm Phase 2 trial to treat other liver cancers.

Outside of the United States, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe. In October 2012, we satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT System for Doxorubicin).

In the United States, our proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). We submitted our New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and are seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver. Our NDA was accepted for filing by the FDA on October 15, 2012 and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013.

About The CHEMOSAT/Melblez Kit Systems

The CHEMOSAT/Melblez Kit systems administer concentrated regional chemotherapy to the liver. This "whole organ" therapy is performed by first isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body's circulatory system, administer a 30 minute infusion of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect drug-laden blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby minimizing systemic exposure to the drug and related toxic side-effects before the filtered blood is returned to the patient's circulatory system. Through December 31, 2012, the CHEMOSAT/Melblez Kit system has been used on approximately 200 patients through clinical development and early commercial experience in Europe.

Currently there are few effective treatment options for cancers in the liver. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, isolated hepatic perfusion and liver transplant. Based on the results of our Phase I, Phase 2 and Phase 3 trials, we believe the CHEMOSAT/Melblez Kit system may address the limitations of traditional treatments for metastatic and primary liver cancers by providing the following advantages, namely:

- *Concentrated Dosing*—Our CHEMOSAT/Melblez Kit system takes advantage of the fact that tumors in the liver obtain their blood supply primarily from the hepatic artery, as opposed to normal hepatic tissue which are supplied by the hepatic portal vein. By directly administering melphalan in the hepatic artery, the CHEMOSAT/Melblez Kit system achieves melphalan blood concentration in the liver estimated to be over 100 times of that achievable by conventional systemic administration. Our Phase 3 clinical trial on patients with metastatic ocular and cutaneous melanoma showed a significant 5.3 months improvement in the study's primary endpoint of hepatic progression free survival (hPFS) for patients treated with the CHEMOSAT/Melblez Kit system as compared to patients treated with best alternative care (BAC).

- *Minimizes Toxicities*—Our Phase 3 clinical trial demonstrated that the Generation One version of the CHEMOSAT/Melblez Kit system was capable of extracting on average 72% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs and minimizes the toxic effects of these chemotherapeutic agents. The Generation Two version of the CHEMOSAT/Melblez Kit system has demonstrated reduced systemic toxicities and impact to blood components in initial commercial use.

- *Minimally Invasive and Repeatable*—The CHEMOSAT/Melblez Kit system allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter than surgical resection or isolated hepatic perfusion.

- *Whole Organ Therapy*—By introducing the chemotherapeutic agent into the arterial blood supply feeding the liver, the CHEMOSAT/Melblez Kit system perfuses the entire liver with chemotherapy, treating both tumors that are visible as well as "micro metastases" that are too small to be detected by imaging.

Strategy

We believe the CHEMOSAT/Melblez Kit system represents a potentially important advancement in regional therapy for cancers in the liver, including both primary liver cancer and metastatic liver cancer with tumor cells originating from other organs. We are seeking to establish the CHEMOSAT/Melblez Kit system as the standard of care for disease control in the liver.

We also intend to develop the system for use with other chemotherapeutic agents, as well as for other organs in addition to the liver. We are continuing our research and development efforts with respect to other chemotherapeutic agents and the treatment of other types of cancer and will need to conduct additional clinical trials and seek approval for escalating doses of anti-cancer agents, including melphalan and doxorubicin for use with the CHEMOSAT/Melblez Kit system.

Our strategy includes the following elements:

- *Obtain FDA Approval for Use of the Melblez Kit to Treat Metastatic Ocular Melanoma in the Liver*. Our NDA was accepted for substantive review by the FDA on October 15, 2012, and the FDA has assigned a PDUFA goal date of June 15, 2013. An Oncologic Drugs Advisory Committee (ODAC) panel will be convened May 2, 2013 as part of the FDA's review. We continue to work closely with the FDA throughout the review process.

- *Commercialize the Melblez Kit in the United States.* If we obtain FDA approval of our NDA, we intend to market our product under the proposed trade name Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System). Our initial marketing efforts will be focused on major cancer centers beginning with those hospitals that participated in our Phase 3 clinical trial. Assuming we obtain approval by the PDUFA goal date of June 15, 2013, we anticipate launching U.S. commercialization efforts in the fourth quarter of 2013.

- *Commercialize the CHEMOSAT Delivery System for Melphalan in the European Economic Area.* We introduced the CHEMOSAT Delivery System for Melphalan in the EEA in early 2012, and have since entered into training and marketing agreements with 16 leading European cancer centers. As of December 31, 2012 eight of these centers have been trained and activated to provide treatment with the CHEMOSAT Delivery System for Melphalan. To date these activated centers have treated patients with a variety of cancers in the liver, including ocular and cutaneous melanoma liver metastases, primary liver cancers, and liver metastases from Cholangiocarcinoma, breast cancer, gastric cancer, colorectal cancer, neuroendocrine tumors, and mucosal melanoma. In the EEA, we are focused on seven target markets: Germany, United Kingdom, Italy, the Netherlands, France, Spain, and Ireland. We market the CHEMOSAT System for Melphalan in Germany, United Kingdom, Ireland and the Netherlands through a direct sales force, have entered into distribution agreements in Italy and Spain, and continue to seek a qualified distributor in France. We have also retained a contract field-based team of medical science liaisons (MSL) to educate the medical oncology community in all seven target markets.

- *Leverage CE Marks to commercialize CHEMOSAT Delivery Systems in Other Countries*. Since obtaining the right to affix the CE Mark to the Generation Two CHEMOSAT System for Melphalan in April 2012, we have successfully applied for regulatory approval of this system in Australia, and completed the product notification process in New Zealand. During 2012 we also submitted applications for regulatory approvals for the CHEMOSAT System for Melphalan in Hong Kong, Singapore, Argentina, and Brazil, and expect to receive approvals in most of these markets in 2013. We also intend to submit additional applications in China, India, Japan, Russia, Taiwan, Israel, and Mexico.

- *Obtain Approval to Market the Melblez Kit in the United States for the Treatment of Other Cancers in addition to Metastatic Ocular Melanoma in the Liver. We concluded a multi-arm Phase 2 trial to evaluate the Melblez Kit for the treatment of other cancers in the liver, such as tumors of neuroendocrine, colorectal adenocarcinoma and cholangiocarcinoma origin that have spread to the liver, as well as primary liver cancer. In 2013, we intend to conduct additional Phase 3 and Phase 2 clinical trials in primary liver cancer, advanced colorectal cancer, and neuroendocrine tumors with liver dominant disease subject to further discussion with the FDA. Assuming successful outcomes of the related clinical trials, we intend to apply for regulatory approval of additional indications.*

- *Expand the Application of Our Technology. In October 2012, we satisfied all of the requirements to affix the CE Mark to the CHEMOSAT System for Doxorubicin. We believe this provides a regulatory pathway for the CHEMOSAT Delivery System to deliver and filter doxorubicin for countries in Asia, particularly China and South Korea where doxorubicin is approved, that accept the CE Marking as part of their national regulatory requirements. We intend to evaluate a variety of chemotherapeutic agents for use with our device platform to treat liver cancers, as well as other organs and body regions.*

- *Establish Strategic Alliances and Distribution Partners. In addition to our existing partnership with Chi-Fu Trading Co., Ltd in Taiwan, we are pursuing strategic partners to develop certain Asian markets including China, South Korea and Japan. We are also pursuing distribution partners to commercialize the product in other Asia-Pacific-Latin American (APLA) markets including Australia, New Zealand, Brazil and Argentina.*

The Cancer Treatment Landscape

Background

According to the American Cancer Society's (ACS) *Cancer Facts & Figures 2013* report, cancer is the second leading cause of death in the United States, with an estimated 580,350 deaths and 1,660,290 new cases expected to be diagnosed in 2013. Cancer is also the second leading cause of death worldwide, accounting for approximately 7.6 million deaths and 12.7 million new cases in 2008 according to GLOBOCAN. The financial burden of cancer is enormous for patients, their families and society. The National Institutes of Health (NIH) estimates that the overall costs of cancer in 2008 were $201 billion: $77 billion for direct medical costs (total of all health expenditures) and $124 billion for indirect mortality costs (cost of lost productivity due to premature death).

Liver Cancers—Incidence, Mortality and Cost

There are two types of liver cancers: primary live cancer and liver metastases. Primary liver cancer (hepatocellular carcinoma or HCC, including intrahepatic bile duct cancers) originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease such as, hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Liver metastases, or secondary liver cancer, is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological function of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize in their liver. In the United States, liver cancer that has metastasized to the liver is more prevalent than primary liver cancer.

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Once ocular melanoma has spread to the liver, evidence suggests median overall survival for these patients is generally 3-6 months. According to the ACS, the annual incidence of ocular melanoma is approximately 2,800 cases per year, with an estimated 320 deaths. Currently there is no standard of care for patients with ocular melanoma liver metastases.

Cutaneous melanoma is expected to be diagnosed in approximately 76,690 persons in 2013 according to the ACS, accounting for less than 5% of all skin cancer cases but the vast majority of skin cancer deaths. Cutaneous melanoma incidence rates in the U.S. have been increasing for at least 30 years. From 2005 to 2009, incidence rates in the U.S. among whites increased by 2.8% per year. An estimated 9,480 deaths from melanoma will occur in the U.S. in 2013. Cutaneous melanomas with deep invasion or that have spread to lymph nodes may be treated with surgery, immunotherapy, chemotherapy, and/or radiation therapy. Advanced cases of cutaneous melanoma are treated with palliative surgery, immunotherapy, and/or chemotherapy, and sometimes radiation therapy. The molecular targeting drug vemurafenib (Zelboraf) and the immunodulator ipilimumab (Yervoy) have recently been approved by the FDA based on improved survival in patients with advanced cutaneous melanoma. Cutaneous melanoma can spread to any part of the body. Studies have shown that metastatic cutaneous melanoma has a 54-77% of spreading to the liver, and the prognosis for these patients is generally poor.

Neuroendocrine tumors (NETs) belong to a family of solid malignant neoplasms that are believed to originate from neuroendocrine cells found throughout the body. NETs are more prevalent than many GI malignancies, including stomach and pancreatic cancer combined, with more than 100,000 cases estimated in the United States. Unfortunately, NETs are often not diagnosed before they metastasize, with 50% of all patients with reported disease stage have either regional or distant metastases at diagnosis. We estimate that up to 40% of patients with NETs will develop liver metastases. Treatment options available to manage these patients include surgical resection, medical, radiologic, and nuclear medicine methods. Two systemic agents, Afinitor (everolimus) and Sutent (sunitinib), are approved for the treatment of advance pancreatic NETs, but these drugs have not been specifically evaluated for metastatic NETs in the liver.

HCC is one of the most prevalent and lethal forms of cancer. According to the American Cancer Society's (ACS) *Cancer Facts & Figures 2013*, an estimated 30,000 new cases of HCC (including intrahepatic bile duct cancers) are expected to occur in the U.S. during 2013, and the five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. Globally, HCC is the second leading cause of cancer death in men and the sixth leading cause of cancer death among women, according to GLOBOCAN 2008. GLOBOCAN estimated approximately 750,000 new HCC cases worldwide in 2008, with approximately 696,000 deaths. Early stage HCC can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Surgical treatment of early stage HCC is often limited by pre-existing liver disease that has damaged the portion of the liver not affected by cancer. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor. Fewer treatment options exist for patients diagnosed at an advanced stage of the disease. Sorafenib (Nexavar) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery.

Colorectal cancer (CRC) is the third most common cancer in both men and women in the U.S. according to ACS. The ACS projects approximately 140,000 new cases of CRC to occur in the U.S. in 2013, with 50,000 deaths resulting from the disease, or 9% of all cancer deaths. Though incidence rates for CRC have been declining in the U.S. due to aggressive screening for the disease in at risk populations, the disease continues to be a significant cause of mortality once it has spread to the liver. We estimate that approximately 50-60% of patients with CRC will have liver metastases, and intend to conduct further research into the potential of the CHEMOSAT/Melblez Kit system for these patients. Surgical resection is considered the most effective treatment for patient with liver metastases from CRC, but only 20% of patients are candidates for resection. Several targeted therapies are approved by the FDA to treat metastatic colorectal cancer: bevacizumab (Avastin) and ziv-aflibercept (Zaltrap) block the growth of blood vessels to the tumor, and cetuximab (Erbitux) and panitumumab (Vectibix) block the effects of hormone-like factors that promote cancer growth.

Liver Cancer Treatment—Common Current Approaches

Traditional treatment options for liver cancers include surgery, chemotherapy, radiation therapy, ablation and chemoembolization and radioembolization, as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgical isolated hepatic perfusion and liver transplant. As is the case with treatment of many other cancer histologies, these options have limited efficacy and are associated with significant side effects. Some of the most frequently used treatments are:

Surgery

Surgical Resection— surgical removal of the diseased portion of the liver—offers the greatest chance of curative treatment for localized cancers and is the preferred method to treat liver cancer once detected. Frequently, symptoms of liver cancer do not appear until the tumors have spread broadly within the liver, making surgical resection impractical. As a consequence, only about 10%-20% of primary and metastatic liver tumors can be surgically removed. Additionally, recurrence of tumors is common, and in that event surgical resection typically cannot be repeated.

Systemic Chemotherapy

Systemic chemotherapy uses anti-cancer drugs that are injected into a vein or given by mouth to destroy cancer cells. The effectiveness of this treatment option often depends upon the dose of chemotherapeutic drug administered. Generally, the higher the dosage of chemotherapy administered, the greater its ability to kill cancer cells. Due to the toxic side effects of chemotherapy agents, the higher the dosage administered, the greater the damage caused to healthy tissues. The high doses of chemotherapy often required to kill cancer cells are highly toxic and may even be lethal to patients.

Radiation Therapy

External beam radiation therapy (XRT) uses high dose x-rays or the delivery of localized radiation to kill cancer cells. A number of localized radiation delivery mechanisms are currently being used and tested, and may demonstrate some effectiveness against certain types of liver cancers. Radiation therapy using x-rays is rarely used for treating liver cancer due to toxicities that impact healthy tissue.

Radioembolization

Selective Internal Radiation Therapy (SIRT) or radioembolization, is a focal therapy that involves the percutaneous, catheter delivery of tiny beads or microspheres that contain a radioactive isotope directly to the liver where they lodge in small vessels in order to deliver radiation to the tumor. Due to the microspheres cutting off blood supply to the healthy liver tissue, the treatment is only applicable for certain, specific tumors that can be visualized, as it is not possible to treat the entire liver where both visible and invisible tumor lesions may be present.

Chemoembolization

Chemoembolization or transarterial chemoembolization (TACE) is a commonly used focal therapy that involves the injection of a chemotherapeutic drug in combination with an embolic material to block normal blood flow into tumors in the liver. Blocking blood flow deprives the tumor of essential oxygen and nutrients and ultimately can kill the tumor. Although chemoembolization allows for focal delivery of chemotherapeutic drugs, the drugs cannot be delivered at an escalated dosage level comparable to the levels at which they are delivered with the CHEMOSAT/Melblez Kit system. Furthermore, the treatment is for specific tumors, not the entire region of the liver. The treatment is only applicable for certain specific tumors that can be visualized, as it is not possible to treat the entire liver where both visible and invisible tumor lesions may be present, due to the embolic material cutting off blood supply to the healthy liver tissue.

Ablation Therapies

Radio frequency ablation (RFA) uses electric current to destroy cancerous cells. The procedure utilizes an ultrasound or CT scan to guide several needles into the abdomen through small incisions. The needles are heated with an electric current that burns the tumor and destroys the cancerous cells. Microwave ablation (MWA) is an experimental therapy similar to radio frequency ablation that uses microwaves instead of electrical current to destroy cancerous cells. Since ablation therapies also destroy the healthy tissue in the liver, these procedures are limited to being focal treatments and only treat the visible tumor, not the tumorous region; therefore, they are generally available only to patients with a limited number of smaller unresectable tumors. Cryoablation differs from RFA and MWA in that it uses extreme cold to destroy or damage cancer cells.

Isolated Hepatic Perfusion

Isolated Hepatic Perfusion (IHP) is an open surgical procedure developed in the 1960s, whereby the venous and arterial vasculature of the liver are accessed through surgical incision of the abdomen. The liver is isolated from the general circulation, and high doses of chemotherapy, often melphalan or oxaliplatin, are perfused through the liver, saturating the entire organ. The procedure has shown significant tumor control rates. However, the procedure is associated with significant operation time and prolonged (2-3 weeks) hospital stay. Based on the invasiveness of the procedure and other factors, the therapy cannot be repeated.

Treatment with the CHEMOSAT/Melblez Kit system

Treatment with the CHEMOSAT/Melblez Kit system is also known as *percutaneous hepatic perfusion* (PHP), a minimally invasive, repeatable procedure that evolved from IHP. The CHEMOSAT/Melblez Kit system is designed to address many of the limitations of traditional treatments by permitting the delivery of much higher doses of chemotherapeutic drugs directly to the liver while minimizing the systemic exposure of such drugs. Unlike focal therapies that can only treat a limited number of visible tumors, the CHEMOSAT/Melblez Kit system perfuses the entire liver with chemotherapeutic agent, creating a new treatment option for patients with diffuse liver dominant disease. Unlike traditional systemic chemotherapy, our system concentrates the chemotherapy primarily on the liver and limits the exposure to healthy tissue in other areas of the body.

The most advanced application for which the CHEMOSAT/Melblez Kit system was evaluated is treatment of metastatic melanoma in the liver. The CHEMOSAT/Melblez Kit system isolates the liver from the patient's general circulatory system, allowing for infusion of highly concentrated doses of chemotherapeutic drugs directly to the isolated liver. The CHEMOSAT/Melblez Kit system then captures and diverts the flow of blood exiting the liver, which contains high doses of chemotherapeutic agents. The blood passes through proprietary filters located outside of the body that remove the majority of the chemotherapeutic agents from the blood before reintroducing it to the patient's general circulatory system. The chemotherapeutic agent remaining in the bloodstream after filtration is a fraction of the infused drug, resulting in manageable toxicities. During our clinical trials, the procedure typically took approximately two to three hours. Patients remained in the intensive care unit overnight for observation after undergoing treatment with the CHEMOSAT/Melblez Kit system. Treatment with CHEMOSAT/Melblez Kit system is a repeatable procedure, and during our clinical trials patients received an average of three procedures at approximately four to six week intervals. A new disposable CHEMOSAT/Melblez Kit system is used for each treatment.

The side effects caused by the drug used in our clinical trials, melphalan, are similar to the side effects associated with delivery of melphalan by traditional methods.

The CHEMOSAT/Melblez Kit system includes the following disposable components:

- Infusion catheter—an arterial infusion catheter used to deliver chemotherapy to the liver.
- Isolation and aspiration catheter—a multi-lumen catheter containing two low-pressure occlusion balloons which are positioned to isolate and capture the blood flow from the liver.
- Filtration circuit outside the body—a blood tubing circuit containing disposable components used with a non-disposable blood pump which push the isolated blood through proprietary filters and deliver the filtered blood back to the patient.
- Filters—external hemofiltration filters remove most of the chemotherapy agent from the isolated blood coming out of the liver before the blood is returned to the patient's general circulatory system.
- Return catheter—a thin-walled blood sheath used to deliver the filtered blood from the filtration circuit outside the body back into the patient's general circulatory system. Series of introducers and related accessories to properly place the catheters.
- In the United States, melphalan hydrochloride for injection will be included with the system.
- In Europe, the system is sold separately and is intended to be used in conjunction with melphalan hydrochloride which is already commercially available from a third party.

Our Clinical Trials

Our Phase 3 trial and our multi-arm Phase 2 trial of the CHEMOSAT/Melblez Kit system with melphalan in patients with liver cancers are summarized below. The Phase 3 and Phase 2 clinical trials were subject to the terms and conditions of the Cooperative Research and Development Agreement (CRADA), between the Company and the National Cancer Institute (NCI). The Phase 3 trial was conducted under an FDA Special Protocol Assessment (SPA) and was conducted at centers throughout the United States.

Phase 3—Melanoma Metastases Trial

In February 2010, the Company concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melblez Kit system, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately four to six week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the treatment arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, the Company announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melblez Kit system for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival, or hPFS. An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization (ECCO) and the European Society of Medical Oncology (ESMO) in September 2011. Data submitted to the FDA in Delcath's NDA comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the treatment group had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the BAC control group, according to the Independent Review Committee (IRC) assessment. This reflects a 4-fold increase of hPFS over that of the control arm, with 50% reduction in the risk of progression and/or death in the PHP treatment group compared to the BAC control group.

Phase 2 Trial

In addition to the Phase 3 metastatic melanoma clinical trial, the Company also concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using the Melblez Kit in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), hepatocellular carcinoma (primary liver cancer or HCC), ocular or cutaneous melanoma, and metastatic colorectal adenocarcinoma (mCRC). In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 42%, with 66% of patients achieving hepatic tumor shrinkage and durable disease stabilization. In the primary liver cancer cohort, a positive signal in hepatic malignancies was observed in 5 of 8 patients. In the mCRC cohort, there was inconclusive efficacy possibly due to advanced disease status of the patients. Similar safety profiles were seen across all tumor types studied in the trial.

Expanded Access Program

In June 2012, we amended our Expanded Access Program (EAP) in the United States to include the use of our Generation Two hemofiltration cartridge of Melblez Kit system. The amendment filed with the FDA permit physicians at experienced U.S. cancer centers to use the Generation Two Melblez Kit system in expanded access and compassionate use cases. Under the EAP's protocol, eligible patients will be able to receive treatment through enrollment at participating cancer centers upon receipt of each center's institutional review board (IRB) approval. The first patient was treated under our EAP in January 2013.

Clinical Development Program

Our Clinical Development Program (CDP) includes plans to evaluate our CHEMOSAT/Melblez Kit system with melphalan for use in the treatment of hepatocellular carcinoma (HCC or primary liver cancer), metastatic colorectal cancer (mCRC) and neuroendocrine tumors with liver dominant disease in future clinical trials, subject to agreement with the FDA. We also plan to collaborate with our strategic partner, in Taiwan, Chi-Fu Trading Co., Ltd, on a pivotal trial with melphalan for HCC. In addition, we obtained the right to affix the CE Mark to the CHEMOSAT Delivery System for Doxorubicin, which we intend to evaluate for use in the treatment of HCC in new clinical trials in People's Republic of China. We anticipate utilizing strategic partners to conduct any trials in China. We intend to initiate certain new clinical trials in these cancers in 2013. We also plan to initiate a Patient Registry in the EU, which will prospectively collect data from EU commercial experience, and expect to support other Investigator Initiated Trials (IIT) globally as suitable opportunities present. The goal of our CDP is to expand our label indication beyond the initial indication we are seeking in ocular melanoma liver metastases. Longer term, we also intend to evaluate a variety of chemotherapeutic agents for use with our technology to treat other liver cancers, as well as other organs and body regions.

In June 2012, we amended our Investigational New Drug (IND) application, which permits the use of the Generation Two CHEMOSAT/Melblez Kit system in the clinical trials we have planned in our CDP.

Strategic Alliances and Distribution Partners

We plan to seek one or more corporate partners in other markets outside the United States, including Asia where we intend to pursue strategic partners to develop markets in China, Korea and Japan. Asia represents a potentially large market for the Delcath CHEMOSAT Delivery System for Doxorubicin, with its primary liver cancer or HCC incidence accounting for an overwhelmingly large majority of the world's primary liver cancer patients. We also intend to leverage our CE Mark in order to expedite approval in select countries, as we have already done successfully in Australia and New Zealand. We believe distribution or corporate partnering arrangements in select markets internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target. We have secured distribution partners in Taiwan, Hong Kong Argentina, and are actively pursuing distribution partners to commercialize the product in other foreign markets including Australia/New Zealand, Mexico, Brazil, and Colombia.

In February 2010, the Company entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd., a Taiwanese company. Under the agreement Chi-Fu will conduct clinical studies of the CHEMOSAT Delivery System for Melphalan and, upon obtaining the approval from the Taiwan Food and Drug Administration (TFDA), will market, sell and distribute CHEMOSAT Delivery System for Melphalan in Taiwan for TFDA indications of use and possibly Singapore.

We believe that our proprietary device platform may have broader applicability, including using other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. As such, we also intend to pursue U.S. pharmaceutical partners to co-develop and fund possible additional indications for our technology.

Sales and Marketing

European Economic Area

In April 2012, we obtained authorization to affix a CE Mark for Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE mark allows us to market and sell the CHEMOSAT Delivery System for Melphalan in the European Economic Area (EEA). In the EEA, the CHEMOSAT Delivery System for Melphalan is regulated as a medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return.

We believe the CHEMOSAT Delivery System for Melphalan may ultimately fulfill an annual unmet clinical need for as many as 55,000 liver cancer patients in the EEA. We are focusing our initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. We believe these countries represent a majority of the total potential liver cancer market in EEA countries. We initially made available the Generation One CHEMOSAT Delivery System for Melphalan in EEA in January 2012, and introduced the Generation Two CHEMOSAT Delivery System for Melphalan in April 2012. Since launching the CHEMOSAT Delivery System for Melphalan, we entered into training and marketing agreements with 16 leading European cancer centers located in all seven of our target markets. As of December 31, 2012, eight of these centers have been trained and activated to provide treatment with the CHEMOSAT System. To date these activated centers have treated patients for a variety of cancers in the liver, including ocular and cutaneous melanoma liver metastases, primary liver cancers, and liver metastases from Cholangiocarcinoma, breast cancer, gastric cancer, colorectal cancer, neuroendocrine tumors, and mucosal melanoma. We are using a combination of direct and indirect sales channels to market and distribute the CHEMOSAT Delivery System for Melphalan in the EEA. To support our commercialization efforts in the EEA, we have established our European Headquarters in Galway, Ireland.

Our commercialization strategy in Europe is comprised of direct and indirect marketing. In Germany, United Kingdom, Ireland and the Netherlands we have established a direct sales force and support teams to market and sell the CHEMOSAT System for Melphalan. In the remainder of the seven target EU markets, we have entered into distribution agreements in Italy and Spain, and continue to seek a qualified distributor in France. To further support our efforts, we have engaged a contract organization to provide Medical Science Liaisons (MSLs) to educate physicians in all seven target markets.

Under the regulatory scheme in the EEA, the CHEMOSAT Delivery System for Melphalan has received authorization to affix the CE Mark as a device only, and physicians must separately obtain melphalan for use with the CHEMOSAT Delivery System for Melphalan. Our ability to market and promote the CHEMOSAT Delivery System for Melphalan is limited to this approved indication. Melphalan is currently approved in 14 member states of the EEA, including the seven markets we are initially targeting.

However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use the CHEMOSAT Delivery System for Melphalan must obtain and use melphalan independently at their discretion.

European Reimbursement

In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis and we have engaged a third party reimbursement specialist to support our efforts in filing for reimbursement coverage. Medical devices are typically reimbursed under diagnosis related groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes.

In Germany, the Institut für das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a reimbursement pathway for the treatment of patients with liver metastases with the CHEMOSAT System for Melphalan. The decision by the InEK followed an endorsement by the German Radiology Association, which prompted 47 cancer centers throughout Germany to submit applications under the Neue Untersuchungs- und Behandlungsmethoden (NUB) scheme for new technology reimbursement at specific hospitals. In February 2013, we announced that the Value 4 status given to procedures with the CHEMOSAT System for Melphalan, while not mandating reimbursement, allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Under the NUB scheme, reimbursement pathways will potentially be available for treatment with CHEMOSAT regardless of primary cancer origin. Some of the participating cancer centers in Germany are pursuing reimbursement under the NUB scheme, and have begun negotiations with private payors.

In the United Kingdom, leading cancer centers are seeking to gain Primary Care Trust (PCT) funding for procedures with the CHEMOSAT Delivery System, which we hope will be granted in the second quarter of 2013. PCT funding would allow CHEMOSAT procedures to be performed at three to four key centers in the United Kingdom, with referrals being made nationwide. We are working closely with five of the key melanoma centers in the United Kingdom to achieve this interim funding. Due to current healthcare reforms in the United Kingdom, in April 2013 interim funding for oncological procedures will move away from local PCTs to a centralized body, which may offer an opportunity to gain nationwide interim funding more quickly. We are also engaged with the Healthcare Resource Groups (HRG) that decide on new HRG codes with a view to gaining a dedicated and permanent reimbursement code. At the same time, the National Institute for Clinical Excellence (NICE) may decide to conduct a review of the CHEMOSAT procedure at any time, the outcome of which would determine our long term reimbursement status. However, we do not anticipate an assessment from NICE until a significant number of CHEMOSAT procedures are conducted regularly in the United Kingdom.

In Italy, we identified an existing DRG code that allows hospitals to submit for partial reimbursement of the CHEMOSAT device and related procedure. Additionally, we are actively assisting hospitals in applying for supplemental new technology payments from certain regions, and are hopeful the authorities in the Lombardy region will issue their decision soon. Furthermore, in conjunction with the European Institute of Oncology in Milan, we are evaluating the potential application for a new dedicated DRG code specific to the CHEMOSAT procedure.

In France, in order to obtain a permanent DRG code, the level of required data both in terms of clinical trials and healthcare economics is extremely high compared to other countries in the EU. We believe we will need the published Phase 3 trial manuscript, supported by investigator initiated trial data before submitting our application. We anticipate submitting our application in late 2013, and in the meantime we are targeting the private market in France.

In Spain, a serious economic crisis and a regionally fragmented reimbursement system are presenting challenges to the introduction of a high-value treatment like the CHEMOSAT Delivery System for Melphalan. However, we anticipate starting procedures at two of the most important centers in Spain, and we hope that this will add momentum for further expansion in this market.

The Netherlands is currently reforming its healthcare system, and in the process has moved to a procedure code driven DRG system, referred to as “DOT” in the Netherlands. The process of obtaining a DOT code specific to the CHEMOSAT Delivery System for Melphalan requires that Delcath publishes its Phase 3 data, which we anticipate submitting for publication in the Spring of 2013. Following publication, our application will be submitted. In the meantime, we are in close contact with the Dutch committee which sanctions new oncological treatments (BOM) and we believe that the CHEMOSAT Delivery System for Melphalan will have a positive review. Until that time we are pursuing the possibility of conducting a limited amount of cases through extraordinary insurance funding at the National Cancer Institute in Amsterdam and at the University Hospital in Leiden.

In the Republic of Ireland, it is our intention to apply for reimbursement once we have assembled sufficient clinical outcomes and economic data via our anticipated EU patient registry, along with publication of our Phase 3 study results. Following submission, CHEMOSAT Delivery System with Melphalan will undergo a review by the National Center for Pharmaeconomics (NCPE) and Health Technological review. The application process allows for a continuous dialogue between Delcath and the assessment body. An initial meeting between the NCPE and Delcath provides a platform to collate documentation on cost effectiveness, budget impact and clinical data. Assuming a positive NCPE appraisal has been passed on to the Health Service Executive (HSE), full adoption of CHEMOSAT Delivery System for Melphalan into the reimbursement system will take an average of 6 months based on typical HSE timelines.

In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

United States

In the United States, if granted FDA approval on or about the PDUFA goal date of June 15, 2013, we intend to begin marketing the Melblez Kit in the fourth quarter of 2013. Our initial marketing efforts will be focused on the hospitals that participated in our Phase 3 clinical trial and our EAP, which provide an existing base of experience procedure teams trained in the use of the Melblez Kit. Our focus will then expand to include other member hospitals of the National Comprehensive Cancer Network (NCCN)—centers of excellence for cancer care in the United States which see a majority of advanced metastatic ocular melanoma patients. To address this market, we plan to deploy a direct sales force supported by MSLs, which will provide clinical-based education to the healthcare professionals (medical oncologists, surgical oncologists, and interventional radiologists) that make up the procedure team utilizing the Melblez Kit.

As with many new products in oncology, the FDA has indicated that if approved the Melblez Kit will have a Risk Evaluation & Mitigation Strategies (REMS) program, which will provide required training to all participants in the procedure utilizing the Melblez Kit. The REMS program will educate procedure team members on elements of safe use and training compliance.

With our anticipated initial indication in ocular melanoma metastasized to the liver, we have begun a comprehensive pricing analysis for this “ultra-orphan” disease state. There are currently no approved or effective treatment options for ocular melanoma metastasized to the liver, so there is a clear unmet clinical need among patients suffering from this disease. Our pricing analysis is aimed at optimizing value for treatment with the Melblez Kit, establishing the economic basis for reimbursement, and ensuring patient access to treatment.

While our initial commercial focus will be on ocular melanoma liver metastases, we will aggressively seek to expand our clinical footprint to include other disease states by pursuing the clinical trials in our current CDP and by support investigator research as opportunities present.

U.S. Reimbursement

In the United States, payors consist of government and private organizations, such as Medicare, Medicaid, private health insurance plans, managed care organizations and other similar entities. To establish reimbursement for any new healthcare product, three elements are necessary:

- Coding-the "why" and "what" to report when a procedure is performed
- Coverage-the terms and conditions under which payors will or will not provide payment
- Payment-the amount of monetary compensation allocated to providers who uses the technology

Assuming our NDA is approved by the FDA, we intend to seek to have payors establish policy coverage and payment of the cost of the Melblez Kit and the associated procedures. Following FDA approval, we intend to apply for a Current Procedural Terminology (CPT) code. A CPT code accurately describes medical, surgical, and diagnostic services, and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. We anticipate submitting an application for a CPT-Category I code in October 2013, if our NDA is approved by the PDUFA goal date. Category I codes represent procedures considered consistent with contemporary medical practice, Category II codes are used for supplemental tracking and Category III codes are used for new and emerging technologies. Assuming an October 2013 submission, the CPT would become effective in January 2015. In the interim, we will assist hospitals in the utilization of existing procedure related codes to obtain reimbursement for treatments utilizing the Melblez Kit.

We also intend to apply for new International Statistical Classification of Diseases and Related Health Problems (ICD-10) procedure codes, which are the standard diagnostic codes for epidemiology, health management and clinical purposes. The ICD-10 codes are used to monitor the incidence and prevalence of diseases and other health problems, and will assist us in capturing costs for the full procedure of hepatic isolation, drug infusion, and filtration. Additionally, as PHP differs from other hepatic therapies, we plan to seek new Diagnosis-related group (DRG) codes, which are used to classify hospital cases expected to have similar hospital resource use. We believe that new DRG codes specific to the Melblez Kit will more accurately reflect hospital costs and aid in achieving sufficient reimbursement.

It is our goal to pursue specific codes that both describe and reflect the therapeutic value provided by the Melblez Kit for patients with ocular melanoma liver metastases. The expert pricing analysis we are conducting will assist us in developing a strategy for reimbursement that maximizes reimbursement for the Melblez Kit. We are also compiling data comparing the Melblez Kit with other cancer treatments for ultra-orphan diseases, which we believe will help illustrate the relative procedure costs and expected therapeutic value of the Melblez Kit and support our efforts to secure coding, coverage and payment.

Government-sponsored reform to the healthcare system aimed at reducing costs is being implemented, and third-party payors are also increasingly adjusting payment rates, often downwards, and challenging the prices charged for medical products and services. There can be no assurance that the Melblez Kit will be covered by third-party payors, that reimbursement will be available, or, if available, that the coverage will be adequate.

Manufacturing and Quality Assurance

We manufacture certain components including our proprietary filter media, and assemble and package the CHEMOSAT/Melblez Kit system at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. Delcath currently utilizes third-parties to manufacture some components of the CHEMOSAT/Melblez Kit system. The CHEMOSAT/Melblez Kit system and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process.

The Company is committed to providing high quality products to our customers. To honor this commitment, Delcath has implemented updated quality systems throughout our organization. Delcath's quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. These systems are designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization (ISO) with respect to products sold in the EEA. The Company is required to maintain ISO 13485 certification for medical devices to be sold in the EEA, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. On February 17, 2011, the Company announced that it had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, the Company announced that it had achieved ISO 13485 certification for our Galway, Ireland facility.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of the global economic downturn, which is affecting healthcare budgets and reimbursement.

The CHEMOSAT/Melblez Kit system competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In each of the disease states we are targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of focal and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covedian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others. For cutaneous melanoma, the targeted drug vemurafenib (Zelboraf, Genetech) and the immunotherapy drug ipilimumab (Yervoy, Bristol-Myers Squibb) have recently been approved by the FDA based on improved survival in patients with advanced metastatic melanoma. For HCC, sorafenib (Nexavar, Onyx Pharmaceuticals) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery. For CRC, several targeted therapies are approved by the FDA to treat metastatic colorectal cancer: bevacizumab (Avastin, Genetech) and ziv-aflibercept (Zaltrap, Sanofi-Aventis) block the growth of blood vessels to the tumor, and cetuximab (Erbitux-Bristol-Meyers Squibb) and panitumumab (Vectibix, Amgen) block the effects of hormone-like factors that promote cancer growth. For NET, treatments include targeted therapies such as sunitib (Sutent, Pfizer), and everolimus (Afinitor, Novartis). Many of these treatments are approved in Europe and other global markets.

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, regulatory, manufacturing and commercialization capabilities. Our competitors may develop more effective or more affordable products or treatment methods, or achieve earlier product development, in which case the likelihood of our achieving meaningful revenues or profitability will be substantially reduced.

Regulatory Environment

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

European Regulation

In order for our products to be marketed and sold in Asia, Europe, or other foreign jurisdictions, we must obtain the required regulatory approvals or clearances and comply with the extensive regulations regarding safety, manufacturing processes and quality requirements of the respective countries. These regulations, including the requirements for approvals to market, and the various regulatory frameworks may differ. In addition, there may be foreign regulatory barriers other than approval or clearance.

In the EEA, the CHEMOSAT Delivery Systems are subject to regulation as medical devices. The EEA is composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the CHEMOSAT Delivery Systems are governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT Delivery System for Melphalan on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

Delcath recently changed its Notified Body in Europe and as part of this change the CHEMOSAT Delivery Systems were reclassified from a Class III medical device to a Class IIb medical device. The primary difference between Class III and Class IIb is that for Class IIb medical devices the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

On October 22, 2012, the Company announced that it had satisfied all of the requirements to affix the CE Mark to its Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection. CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Application of the CE Mark for the CHEMOSAT Delivery System for Doxorubicin provides Delcath with a regulatory pathway for certain countries in Asia that accept CE Marking as part of their national regulatory requirements. Doxorubicin is an established chemotherapeutic agent commonly used globally to treat hepatocellular carcinoma (HCC) via trans-arterial chemoembolization (TACE) and is widely used to treat HCC in Asia, which is where the Company sees the market opportunity for our CHEMOSAT Delivery System for Doxorubicin injection. In China, these requirements include conducting a local clinical trial and approval by the China State Food and Drug Administration (SFDA). Delcath intends to seek approvals for the CHEMOSAT Delivery System for Doxorubicin in key Asian markets such as China and South Korea. The Company does not intend to market the CHEMOSAT Delivery System for Doxorubicin in the European Economic Area at this time.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the European Union must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT Delivery System for Melphalan and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission reviewed the medical devices legislative framework in 2012 with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. We do not believe the adopted regulatory changes will impact our business at this time, though future changes to the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

Other International Regulations

We received regulatory approval for the CHEMOSAT System for Melphalan in Australia and completed the product notification process in New Zealand. We have submitted applications for regulatory approval as a device for the CHEMOSAT System for Melphalan in Argentina, Taiwan, Hong Kong, South Korea (CHEMOSAT Delivery System for Doxorubicin), and Singapore. We intend to submit regulatory applications in Israel, Mexico, Brazil, India, Japan, and China (CHEMOSAT Delivery System for Doxorubicin). It is our intention to leverage the CE Mark in some or all of these countries to commercialize the CHEMOSAT Delivery Systems, where appropriate. Our Delcath Systems Limited facility in Galway, Ireland has obtained certificates of free sale from the Irish Medicines Board as many markets require country of origin manufacturing, such as Mexico, Argentina, Brazil, Japan, China, and Taiwan, as a prerequisite to obtain regulatory approval. In Canada, our application for approval as a device was rejected by the Canadian health authority, with the recommendation that we resubmit our application as a drug, similar to the process we are following in the United States. We are currently evaluating this option for seeking regulatory approval in Canada.

United States Regulation

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), and its implementing regulations. The Delcath Melblez Kit is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melblez Kit, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research (CDER), has primary jurisdiction over its pre-market development and review. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- *Phase I Clinical Trials*. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- *Phase 2 Clinical Trials.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3 Clinical Trials.* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- *Phase IV Clinical Trials.* The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase IV clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a Special Protocol Assessment (SPA). A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Prior to initiating our Phase 3 clinical trial, we submitted a proposal for the design, execution and analysis under a SPA, and we conducted our Phase 3 trial under a SPA.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy (REMS) that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

In August 2012, we submitted our NDA for the Melblez Kit under Section 505(b)(2) of the FFDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication we are seeking to ocular melanoma metastatic to the liver. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products, such as melphalan. Melphalan, the drug we are initially seeking to have approved for use with the Melblez Kit, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we used in our Phase 3 clinical trial. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Melblez Kit delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that which is currently approved, we will be seeking a revised label of melphalan for use with the Melblez Kit through its Section 505(b)(2) NDA. The clinical trials were designed to provide the necessary clinical data to support this required labeling change.

For new oncology products, the FDA will often solicit an opinion from an Oncologic Drugs Advisory Committee, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The Company's NDA was accepted for filing by the FDA on October 15, 2012, and has been designated for standard review with a PDUFA goal date of June 15, 2013. An ODAC meeting has been scheduled by the FDA for May 2, 2013.

Following the ODAC panel opinion, the FDA will make its final decision on our NDA. There can be no assurance that the FDA will ultimately approve the Company's NDA.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting. The FDA has granted Delcath four orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. If the Melblez Kit is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity.

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. The Melblez Kit, if approved by the FDA, may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw approval of the NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Thus, we may only market the Melblez Kit, if approved by the FDA, for its approved indications and we could be subject to enforcement action for any off-label marketing.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds six United States patents, nine foreign patents with patent validity in 25 countries, six pending United States patent applications, and fourteen pending foreign patent applications. Our recent foreign patent filings include applications in Argentina, Australia, Brazil, Canada, China, Europe, and Japan.

When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to make patent improvements that we identify through research and development, manufacturing, and clinical use of the CHEMOSAT/Melblez Kit system that will enable us to expand our platform beyond the treatment of cancers in the liver. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. The Company relies, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

Certain of our United States and foreign patents have already expired and other patents relating to the CHEMOSAT/Melblez Kit system will expire in 2016 and 2017. In certain circumstances, United States patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval. In addition to our proprietary protections, the FDA has granted Delcath four orphan drug designations which provides us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, the Company believes that it will provide us with added protection while we commercialize the Melblez Kit in the United States.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against Delcath, the Company may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, Delcath plans to enforce its intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Employees

As of December 31, 2012, the Company had 92 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Available Information

Delcath maintains a website at www.delcath.com. The Company makes available, free of charge on our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after the Company electronically files those reports with, or furnishes them to, the Securities and Exchange Commission, or the SEC. The Company is not including the information contained at www.delcath.com or at any other internet address as part of, or incorporating by reference into, this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks Related to Our Business and Financial Condition

If we are unable to develop the CHEMOSAT/Melblez Kit system, obtain regulatory approval outside the EEA or market and sell the system, we will not generate operating revenue or become profitable.
The CHEMOSAT/Melblez Kit system, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs, is our only product. Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of this product and currently we have only developed this system for the treatment of cancers in the liver. If the CHEMOSAT/Melblez Kit system for the treatment of cancers in the liver fails as a commercial product, we have no other products to sell. In addition, since the Delcath Hepatic CHEMOSAT Delivery System is currently only authorized for marketing in the EEA, Australia and New Zealand, if we are unsuccessful in commercializing the product in these jurisdictions and if the Delcath chemosaturation system is not approved in the United States and elsewhere, we will have no means of generating revenue.

Continuing losses may exhaust our capital resources and our ability to raise additional capital may be limited by global market conditions.
As of December 31, 2012, we had $23.7 million in cash, cash equivalents and certificates of deposit. We have had minimal revenue to date, and we have a substantial accumulated deficit, recurring operating losses and negative cash flow. While we anticipate generating revenue over the next year, we expect to continue to incur losses. For the years ended December 31, 2012, 2011, and 2010, we incurred net losses of approximately $51.9 million, $30.9 million, and $46.7 million, respectively, with these amounts being effected by derivative accounting related to warrants as described in our Annual Reports on Form 10-K for the years ended December 31, 2012, 2011, and 2010. To date, we have funded our operations through a combination of private placements and public offerings of our securities. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of the CHEMOSAT/Melblez Kit system with melphalan or any other versions of the system.

The global financial crisis that began in late 2007 caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. Further deterioration in the global economy and other factors, including the uncertainty surrounding the U.S. federal budget process, beyond our control may adversely affect our ability to obtain financing for developing, commercializing, and obtaining regulatory authorizations and approvals of our product.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to commercialize the CHEMOSAT/Melblez Kit system, continue the NDA review process with the FDA or conduct future development and clinical trials.
We may require additional financing to commercialize our product in the EEA and any other markets where we receive approval for our system, to continue the review process of our NDA with the FDA seeking U.S. marketing approval or seek other approvals and to conduct future development and clinical trials. In addition, we are obligated to make payments under long-term research and development obligations and lease agreements. If financing is unavailable to make the required payments under these agreements, we could be subject to legal liability and our ability to complete our development projects or our clinical trials could be impaired. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to able to commercialize the Delcath chemosaturation system commercially, obtain regulatory approvals or complete our development projects or our clinical trials.

Our liquidity and capital requirements will depend on numerous factors, including:

- our research and product development programs, including clinical studies;
- the timing and costs of our various U.S. and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

The CHEMOSAT/Melblez Kit system continues to be the subject of clinical trials, the results of which may be unfavorable, or perceived as unfavorable by the market, and could have a material adverse effect on our business, financial condition and results of operations.
As a part of the regulatory process of obtaining marketing clearance for the CHEMOSAT/Melblez Kit system, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials or the market's or FDA's perception of this clinical data, may adversely impact our ability to obtain approval, and the financial condition and results of operations.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

The CHEMOSAT/Melblez Kit system is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The CHEMOSAT/Melblez Kit system is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the CHEMOSAT/Melblez Kit system, the primary mode of action is attributable to the drug component of the product, which means that the CDER has primary jurisdiction over its pre-market development and review.

We are not permitted to market the CHEMOSAT/Melblez Kit system in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, we submitted the CHEMOSAT/Melblez Kit system NDA, and the FDA has accepted the NDA for filing and set a PDUFA target date for June 15, 2013. We may not receive approval for the CHEMOSAT/Melblez Kit system on the PDUFA target date or later. The FDA may decide not to approve the CHEMOSAT/Melblez Kit system, may issue a complete response letter, may extend the PDUFA target date, may request additional information or may take various other actions. We may be unable to provide or timely provide any additional information requested by the FDA. The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. Failure to obtain or delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current CHEMOSAT/Melblez Kit system or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the Delcath Hepatic CHEMOSAT Delivery System ("CHEMOSAT System") as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with the Delcath Hepatic CHEMOSAT Delivery System, our ability to commercialize the Delcath Hepatic CHEMOSAT Delivery System in the EEA will be significantly limited.

In the EEA, the CHEMOSAT System is regulated as a Class IIb medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the CHEMOSAT System is limited to this approved indication. To the extent that our promotion of the CHEMOSAT System is found to be outside the scope of our approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize the CHEMOSAT System in the EEA.

We would be limited to marketing the CHEMOSAT System in the EEA as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with the Delcath Hepatic CHEMOSAT Delivery System, our ability to commercialize the Delcath Hepatic CHEMOSAT Delivery System in the EEA will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EEA where the drugs are authorized for marketing. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath CHEMOSAT System and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from our product and/or to prescribe the use of melphalan independently, our sales opportunities in the EEA will be significantly impaired.

While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval.

In April 2011, we obtained the required certification from our European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Delcath Hepatic CHEMOSAT Delivery System. In order to maintain the right to affix the CE Mark in the EEA, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Delcath CHEMOSAT System may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that the CHEMOSAT/Melblez Kit system is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for the CHEMOSAT/Melblez Kit system may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Melblez Kit system by the FDA for use in the United States.

We cannot sell or market the Melblez Kit system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Melblez Kit system. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system. We are seeking approval of the Melblez Kit system for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for the Melblez Kit system with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of the Melblez Kit system with melphalan or any other chemotherapeutic agent or compound we use in our system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company, our results of operations and our ability to raise additional capital will be harmed.

On August 15, 2012, we submitted our Section 505(b)(2) NDA to the FDA. We are seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic ocular melanoma in the liver. An NDA submitted under Section 505(b)(2) of the FFDCA permits the application to incorporate information required for approval from studies not conducted by or for the application and for which the applicant has not obtained a right of reference. Our Section 505(b)(2) application cited the safety information for melphalan submitted by prior NDA applicants for this drug. On October 15, 2012 the FDA accepted our NDA and we received a PDUFA goal date of June 15, 2013. During the review process, if the FDA raises questions or concerns and we are unable to properly address these questions or concerns to the FDA's satisfaction, the FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. In addition, the FDA may extend the PDUFA target date or take other actions beyond our control. If FDA approval is obtained, the approval may be significantly limited to indications for use or may otherwise be limited, which could restrict the ability to commercialize the Melblez Kit system. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions arise after the product reaches the market. Additionally, the FDA may fail to approve the NDA after a substantive review, in which case we will not be able to commercialize the Melblez Kit system in the United States and our value and our results of operations will be harmed.

Even if we obtain regulatory approval for the Melblez Kit system in the United States, our ability to market the Melblez Kit system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. In the United States, we are seeking approval for use of the Melblez Kit system with melphalan in the treatment of ocular melanoma that has metastasized to the liver. If the FDA approves this application, our ability to market and promote the Melblez Kit system would be limited to this indication for use only with melphalan in treating that specific disease, so even with FDA approval, the Melblez Kit system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market the Melblez Kit system, if approved by the FDA, for its approved indication and we could be subject to enforcement action for off-label marketing.

Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If we do not obtain required approvals in the United States and in the countries outside of the EEA in which we aim to market the CHEMOSAT/Melblez Kit system, we may not be able to export or sell the CHEMOSAT/Melblez Kit system in those markets, which will limit our sales opportunities.

We intend to leverage our CE Mark to obtain required regulatory approvals for the Delcath CHEMOSAT System in other parts of the world. We have satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin. We intend to leverage our CE marked doxorubicin system to provide a pathway for regulatory approval in China and South Korea. However, our lack of experience conducting clinical trials outside the United States may negatively impact the approval process in China or other foreign countries where we intend to seek approval for the CHEMOSAT/Melblez Kit system. We have not previously conducted multi-national clinical trials, and, particularly in countries where melphalan has not yet been approved, obtaining approval for the CHEMOSAT/Melblez Kit system may be challenging.

If we are unable to obtain and maintain required approval from one or more foreign countries outside of the EEA where we would like to sell the CHEMOSAT/Melblez Kit system, we will be unable to market our product as intended, our international market opportunity will be limited and the value of our company and our results of operations will be harmed.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the CHEMOSAT/Melblez Kit system for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase III clinical trial of the CHEMOSAT/Melblez Kit system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase II clinical trial of the CHEMOSAT/Melblez Kit system with melphalan in patients with primary and metastatic melanoma stratified into four arms. We currently have no clinical trials on any other major forms of liver cancer.

We intend to conduct clinical trials for other indications, and it may take several years to complete the testing of the CHEMOSAT/Melblez Kit system with melphalan, doxorubicin or other chemotherapeutic agents for use in the treatment of the indications we wish to obtain approval of, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase III trial, relating to our NDA submissions;
- the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause us to cease the development of the CHEMOSAT/Melblez Kit system for other indications. If we are unable to develop the CHEMOSAT/Melblez Kit system for other indications the future growth of our business could be negatively impacted. In addition, we have limited clinical data relating to the effectiveness of the CHEMOSAT/Melblez Kit system in certain types of cancer. Such limited data could slow the adoption of our CHEMOSAT/Melblez Kit system, significantly reduce our ability to commercialize the CHEMOSAT/Melblez Kit system.

We rely on third parties to conduct certain of the clinical trials for the CHEMOSAT/Melblez Kit system, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for the CHEMOSAT/Melblez Kit system, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. In particular, we relied on a third party to conduct monitoring of our Phase II and Phase III clinical trials and collect the data for our planned resubmission of an NDA. We intend to rely upon third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements, and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and we may fail to obtain regulatory approval for the CHEMOSAT/Melblez Kit system if these requirements are not met.

Purchasers of the Delcath CHEMOSAT System in the EEA may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, we may not be able to successfully commercialize the Delcath Hepatic CHEMOSAT Delivery System in the EEA.
We have obtained the right to affix the CE Mark for the Delcath CHEMOSAT System, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell the Delcath CHEMOSAT System. In Italy, the CHEMOSAT procedure can be reimbursed under an existing diagnosis related group code, or DRG, which only provides partial coverage. In Germany, we have received approval for Value 4 status reimbursement. Value 4 status does not mandate reimbursement, but allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Consequently, we may not be able to obtain reimbursement, and any reimbursement obtained may not be for the full amount sought. In countries where we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that we will qualify for such funding. Even if we do qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of members states of the EEA will reimburse the product's use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath CHEMOSAT System if they do not receive substantial reimbursement for the cost of using our product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

As the CHEMOSAT/Melblez Kit system is not currently approved by the FDA or other regulatory bodies outside the EEA, Australia or New Zealand, third-party payors in the United States and elsewhere will not reimburse the use of our product. Even if approval is obtained, inadequate reimbursement may harm results of operations.
The CHEMOSAT/Melblez Kit system is currently not approved by the FDA or any other regulatory body outside the EEA, Australia or New Zealand. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the CHEMOSAT/Melblez Kit system's use since the product is currently not approved outside the EEA, Australia or New Zealand. We will seek reimbursement by third-party payors of the cost of the CHEMOSAT/Melblez Kit system after its use is approved, but there are no assurances that third-party payors in the United States or other countries will agree to cover the cost of procedures using the CHEMOSAT/Melblez Kit system at all or at rates that are adequate to cover the actual costs.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize the CHEMOSAT/Melblez Kit system and the demand for the CHEMOSAT/Melblez Kit system. Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies. In March 2010, the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 were enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. It is uncertain what consequences these provisions will have on our efforts to commercialize the CHEMOSAT/Melblez Kit system.

Consolidation in the healthcare industry could lead to demands for price concessions.
The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States result in a consolidation of purchasing decisions for potential healthcare provider customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of the CHEMOSAT/Melblez Kit system and adversely impact our business, financial condition and results of operations.

Further, third-party payors may deny reimbursement if they determine that the CHEMOSAT/Melblez Kit system is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase the CHEMOSAT/Melblez Kit system, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the CHEMOSAT/Melblez Kit system

There is only one approved third-party manufacturer of melphalan in the EEA. If this manufacturer fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EEA.

Under the regulatory scheme in the EEA, the Delcath CHEMOSAT System is approved for marketing as a device only, and doctors will separately obtain melphalan for use with the Delcath CHEMOSAT System. Although melphalan has been approved in the EEA for over a decade, we are aware that there is currently only one approved manufacturer of melphalan in the EEA, with whom we have no supply arrangements or other affiliation, and therefore we will not have any control over the quality, availability, price or labeling of melphalan in that market. As a result, there may not be sufficient supply of melphalan for use with our system, and any adverse change in the sole manufacturer's commercial operations or regulatory approval status may seriously impair our sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where we intend to market the Delcath CHEMOSAT System. If supply of melphalan remains limited or unavailable, we will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

We purchase components for the CHEMOSAT/Melblez Kit system from third parties, some of which are sole-source suppliers.
The components of the CHEMOSAT/Melblez Kit system, including catheters, filters, introducers and chemotherapy agents, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet cGMP and quality systems requirements. Some states also have similar regulations. Many of the components of the CHEMOSAT/Melblez Kit system are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If Delcath or any of our suppliers fails to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials, and, once a product is approved for marketing, the manufacture, assembly or distribution thereof. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for the CHEMOSAT/Melblez Kit system, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply the CHEMOSAT/Melblez Kit system to the market.

All of the manufacturers of the components for the CHEMOSAT/Melblez Kit system must comply with a number of FDA and International Organization for Standardization, or ISO, and foreign regulatory agency requirements and regulations. If we or one of our suppliers fails to meet such requirements, we may need to change suppliers. If we are unable to successfully change suppliers, the successful completion of some of our future clinical trials and/or commercialization of the CHEMOSAT/Melblez Kit system could be jeopardized. The CHEMOSAT/Melblez Kit system and its components must be manufactured and sterilized with approved manufacturing and pre-determined performance specifications. Certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process. A third-party vendor's failure to properly sterilize a component may cause manufacturing or assembly delays.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize the Delcath system in the United States.
We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC, or Synerx, and Bioniche Teoranta, or Bioniche, an affiliate of Mylan, Inc., for the supply of our branded melphalan for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. We intend to pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for the commercialization of the CHEMOSAT/Melblez Kit system, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we would first have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture the CHEMOSAT/Melblez Kit system, our ability to develop and commercialize the system would be impaired.
We manufacture the CHEMOSAT/Melblez Kit system for distribution worldwide in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver the CHEMOSAT/Melblez Kit system to purchasers.

In addition to limiting sales opportunities, delays in manufacturing the CHEMOSAT/Melblez Kit system may adversely affect our ability to obtain regulatory approval in other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture the CHEMOSAT/Melblez Kit system in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble the CHEMOSAT/Melblez Kit system in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

We do not have written contracts with all of our suppliers for the manufacture of components for the CHEMOSAT/Melblez Kit system.
We do not have written contracts with all our suppliers for the manufacture of components for the CHEMOSAT/Melblez Kit system. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of the CHEMOSAT/Melblez Kit system in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of the CHEMOSAT/Melblez Kit system are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of the CHEMOSAT/Melblez Kit system may be delayed.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing the Delcath CHEMOSAT System in the EEA.
We are pursuing a two-pronged commercialization strategy in the EEA under which we directly and indirectly market the Delcath CHEMOSAT System for melphalan. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we utilize a direct sales force to sell our product to interventional radiologists and hospitals. This marketing strategy will be dependent on our ability to maintain and develop relationships with physicians. In Italy and Spain we have entered into an agreement with a third-party distributor in each of these countries and intend to utilize a third party distributor in France. We have entered into an agreement with a contract organization to provide MSLs to educate the medical oncologist in these regions. However, we have not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though we have obtained the right to affix the CE Mark, we currently have limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize the Delcath CHEMOSAT System in the EEA, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If we cannot successfully develop the infrastructure to market and commercialize the Delcath CHEMOSAT System, our ability to generate revenues in the EEA may be harmed, and we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

Competition for sales and marketing personnel is intense, and we may not be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect our business, financial condition and results of operations. Further, since our marketing strategy in the EEA includes establishing a network of third-party distributors, we must enter into collaborative arrangements with these third-party distributors. We may not be able to enter into such arrangements on reasonable terms or at all.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing the CHEMOSAT/Melblez Kit system in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.
Outside the EEA, even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize the CHEMOSAT/Melblez Kit system may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. In the United States, we intend to develop and train our own sales force to market our products, and in foreign countries other than in the EEA, we intend to market our products primarily through strategic partners and distributors. If we are unable to develop this infrastructure in the United States or to collaborate with an alliance partner to market our products in foreign countries, particularly in Asia, our efforts to commercialize the CHEMOSAT/Melblez Kit system or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing the CHEMOSAT/Melblez Kit system in the EEA, we may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so our EEA strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market the Delcath CHEMOSAT System in each of our target markets may fail in any or all of those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell the CHEMOSAT/Melblez Kit system may not be successful.
We have entered into a collaborative agreement with Chi Fu Trading Company for the country of Taiwan and intend to enter into one or more strategic alliances to further address markets outside the United States, particularly in Asia, and to help fund the development of additional indications or for use with additional chemotherapy agents within the United States. We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in our search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all.

Our collaborative relationships may never result in the successful development or commercialization of the CHEMOSAT/Melblez Kit system or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with the CHEMOSAT/Melblez Kit system or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.
Currently we have only received authorization to market the Delcath CHEMOSAT System for melphalan in the EEA, Australia and New Zealand, and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of our products to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to fulfill foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If we fail to overcome the challenges we encounter in our international operations, our business and results of operations may be materially adversely affected.

The Delcath CHEMOSAT System has been used a limited number of times in a clinical setting in the EEA, so market acceptance of our product will depend on EEA healthcare professionals' efforts to learn about our product.
Since all of our prior clinical studies were conducted in the United States and the Delcath CHEMOSAT system has had limited use in a clinical setting in the EEA, physicians in the EEA have no clinical experience with our product. As a result, the Delcath Hepatic CHEMOSAT Delivery System may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors in the EEA until healthcare professionals are properly educated about the procedure. Market acceptance of the CHEMOSAT System in the EEA will depend upon a variety of factors including:

- whether our future clinical trials demonstrate significantly improved patient outcomes;
- our ability to educate and train physicians to perform the procedure and drive acceptance of the use of the CHEMOSAT System;
- our ability to obtain adequate reimbursement and convince healthcare payors that use of the CHEMOSAT System results in reduced treatment costs and improved outcomes for patients;
- whether the CHEMOSAT System replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology's value has been demonstrated.

We intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in the EEA, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop. Without effort from healthcare professionals to become educated about our product, the market may not accept the CHEMOSAT system and our efforts to commercialize the CHEMOSAT system in the EEA may be unsuccessful.

Similar considerations apply in any other market where we receive approval. Successful commercialization of the CHEMOSAT System in these markets will depend on market acceptance by healthcare professionals.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.
Competition in the cancer treatment industry is intense. The CHEMOSAT/Melblez Kit system competes with all forms of liver cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

Our ability to develop the CHEMOSAT/Melblez Kit system for other indications could affect our orphan drug exclusivity. The FDA has granted Delcath four orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. If the CHEMOSAT/Melblez Kit system is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity, which could increase our competition.

The loss of key personnel could adversely affect our business.
The loss of a member of our senior executive staff could delay our obtaining FDA approval, our introducing the CHEMOSAT/Melblez Kit system commercially and our generating revenues and profits. Competition for experienced personnel is intense. If we cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

Risks Related to Patents, Trade Secrets and Proprietary Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and commercialize the CHEMOSAT/Melblez Kit system prior to the expiration of our patent protection.
Our patent portfolio consists of seven U.S. patents, one pending Patent Cooperation Treaty application, 22 issued foreign counterpart patents and four pending foreign counterpart patent applications. Certain of our U.S., European and other foreign patents have already expired and other U.S. patents relating to the CHEMOSAT/Melblez Kit system will expire beginning in 2013 through 2016.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the CHEMOSAT/Melblez Kit system or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our U.S. patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions.

Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Since we rely solely on trade secret protection in the EEA, our inability to maintain this trade secret protection will significantly limit our ability to commercialize the CHEMOSAT/Melblez Kit system in the EEA.
We presently only have valid issued patents for the current version of the CHEMOSAT/Melblez Kit system in the United States. Without patent protection in the EEA, the Delcath CHEMOSAT System will only be covered by trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge or that we will have adequate remedies for any such breach.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to the CHEMOSAT/Melblez Kit system will significantly impair our ability to commercialize the Delcath CHEMOSAT System in the EEA, and our value and results of operations will be harmed. In particular, we rely on trade secret protection for the filter media, which is a key component of our system.

Similar considerations apply in any other foreign country where we receive approval. Since we do not have valid issued patents for the current version of the CHEMOSAT/Melblez Kit system in these countries, our ability to successfully commercialize the CHEMOSAT/Melblez Kit system will depend on our ability to maintain trade secret protection in these markets.

Risks Related to Products Liability

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.
Our business exposes us to potential liability risks that may arise from the testing, manufacture, marketing, sale and use of the CHEMOSAT/Melblez Kit system. In addition, because the CHEMOSAT/Melblez Kit system is intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the use of our system, the patient may be injured through the use of our system, which may subject us to claims. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Our Common Stock

Our stock price and trading volume may be volatile, which could result in unpredictable pricing of our equity securities.
The equity markets may experience periods of volatility, which could result in highly variable and unpredictable pricing of equity securities. The market price of our common stock could change in ways that may or may not be related to our business, our industry or our operating performance and financial condition. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- results of our clinical trials;
- regulatory delays, non-acceptance or non-approval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the CHEMOSAT/Melblez Kit system;
- product recalls;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;
- a challenge to one of our patents, either in court or via administrative proceedings in the United States Patent and Trademark Office;
- conditions generally affecting the healthcare and cancer treatment industries;
- the success of our operating strategy;
- our ability to repay our debt;
- future sales of equity or equity-related securities; and
- general financial, economic, domestic, international and other market conditions.

Many of these factors are beyond our control, and we cannot predict their potential impact on the price of our common stock. We cannot assure you that the market price of our common stock will not fluctuate or decline significantly in the future.

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.
The warrants issued in our June 2009 and May 2012 offerings are subject to an exercise price adjustment upon certain equity issuances below $1.20 per share (as may be further adjusted). In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

Anti-takeover provisions in our Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.
Certain provisions of our Certificate of Incorporation and By-laws and of our stockholders rights agreement could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of our stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We also have a stockholder rights agreement that could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

Our common stock is listed on The NASDAQ Capital Market.
If we fail to meet the requirements of The NASDAQ Capital Market for continued listing, our common stock could be delisted. To keep such listing, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million. We are presently in compliance with these requirements.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ's corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.
If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.
We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.
We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of December 31, 2012, we had an aggregate of 93,150,967 shares of common stock authorized but unissued. Subject to certain volume limitations imposed by The NASDAQ Capital Market, we may issue all of these shares without any action or approval by our shareholders. We have established an "at the market" equity offering program, and we may issue shares under this program without any action or approval by our shareholders. We may expand our business through complementary or strategic acquisitions of other companies and assets, and we may issue shares of common stock in connection with those acquisitions or otherwise. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices currently occupy 17,320 square feet of office space at 810 Seventh Avenue, New York, New York under a lease that expires in March 2021. The Company leases three additional spaces in the US including approximately 18,000 square feet at Suites 2 and 3 Country Club Road, and 6,000 at 95-97 Park Road in Queensbury, New York. The lease agreements expire on June 1, 2015, and July 18, 2014, respectively. Delcath purchased a building at 566 Queensbury Avenue in Queensbury, NY during 2012. These facilities house manufacturing, quality assurance and quality control, research and development, and office space. The Company also owns land at 10, 12 and 14 Park Road in Queensbury, New York. In addition, Delcath Systems Limited leases a facility for office and manufacturing containing approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires August 2, 2021. The Company believes substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs.

Item 3. Legal Proceedings.

None.

Item 4. Removed and Reserved.

Part II

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

Our common stock is traded on The NASDAQ Capital Market under the symbol "DCTH".

The following table sets forth the high and low last reported sales prices of our common stock for the fiscal quarters indicated as reported on The NASDAQ Capital Market:

Common Stock Price Range

	2012	
	High	Low
Quarter ended March 31, 2012	$ 4.60	$ 2.98
Quarter ended June 30, 2012	3.20	1.41
Quarter ended September 30, 2012	2.17	1.62
Quarter ended December 31, 2012	2.31	1.11

	2011	
	High	Low
Quarter ended March 31, 2011	$ 11.44	$ 6.18
Quarter ended June 30, 2011	8.63	4.98
Quarter ended September 30, 2011	6.37	3.09
Quarter ended December 31, 2011	3.75	1.88

On March 11, 2013 there were 133 stockholders of record of our common stock.

Dividend Policy

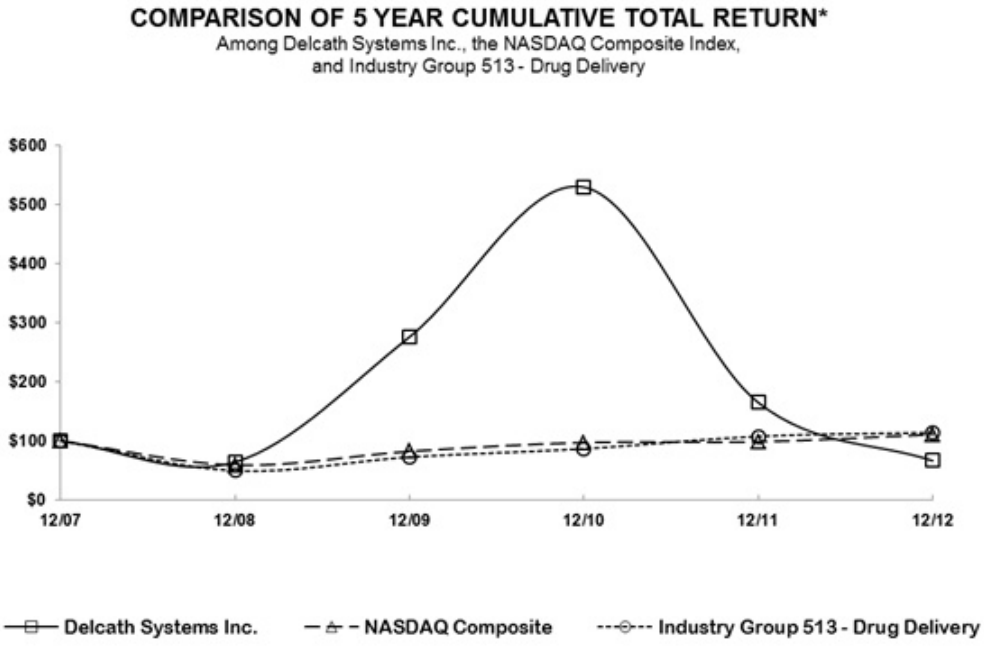
The Company has never declared or paid cash dividends on our common stock and has no intention to do so in the foreseeable future.

Recent Sales of Unregistered Securities

The Company did not sell any equity securities that were not registered under the Securities Act of 1933, as amended, in the years ended December 31, 2012, 2011 and 2010.

Performance Graph

The graph below matches Delcath Systems Inc.'s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the Industry Group 513 - Drug Delivery index. The graph tracks the performance of a $100 investment in our common stock and in each of the indices (with the reinvestment of all dividends) from 12/31/2007 to 12/31/2012.



	12/07	12/08	12/09	12/10	12/11	12/12
Delcath Systems Inc.	**100.00**	**64.32**	**276.22**	**529.73**	**164.86**	**66.49**
NASDAQ Composite	**100.00**	**59.03**	**82.25**	**97.32**	**98.63**	**110.78**
Industry Group 513 - Drug Delivery	**100.00**	**49.38**	**72.70**	**86.72**	**107.78**	**114.19**

	12/07	12/08	12/09	12/10	12/11	12/12
Delcath Systems Inc.		**-35.68%**	**329.41%**	**91.78%**	**-68.88%**	**-59.67%**
NASDAQ Composite		**-40.97%**	**39.32%**	**18.32%**	**1.35%**	**12.33%**
Industry Group 513 - Drug Delivery		**-50.62%**	**47.22%**	**19.29%**	**24.28%**	**5.94%**

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Item 6. Selected Financial Data.

The selected financial data set forth below should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included in this Annual Report on Form 10-K.

The selected financial data set forth below as of December 31, 2012, 2011, 2010, 2009 and 2008 and for the years ended December 31, 2012, 2011, 2010, 2009 and 2008 are derived from our audited financial statements included in this Annual Report on Form 10-K. All other selected financial data set forth below is derived from our audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our results of operations to be expected in the future.

	Year Ended December 31,				
(Dollars in thousands)	**2012**	**2011**	**2010**	**2009**	**2008**
Statement of Operations Data					
Net Sales	$ 346	$ -	$ -	$ -	$ -
Costs and expenses	54,178	46,456	30,743	13,536	8,066
Operating loss	53,871	46,456	30,743	13,536	8,066
Net loss	51,868	30,885	46,684	22,057	6,865
Loss per share	(0.85)	(0.68)	(1.20)	(0.82)	(0.27)

	Year Ended December 31,				
(Dollars in thousands)	**2012**	**2011**	**2010**	**2009**	**2008**
Balance Sheet Data					
Current assets	$ 26,432	$ 31,988	$ 48,898	$ 36,286	$ 11,341
Total assets	30,474	35,241	50,578	36,807	11,359
Current liabilities	10,156	8,837	21,197	13,049	1,152
Stockholder's equity	20,009	26,104	29,081	23,758	10,207

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We are a specialty pharmaceutical and medical device company focused on oncology. Our proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our initial focus is on the treatment of primary and metastatic liver cancers. We believe that the proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, we announced that our randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. We have also completed a multi-arm Phase 2 trial to treat other liver cancers.

Outside of the United States, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe. In October 2012, we satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT System for Doxorubicin).

In the United States, our proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). We submitted our New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and are seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver. Our NDA was accepted for filing by the FDA on October 15, 2012 and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013.

The CHEMOSAT/Melblez Kit system administers concentrated regional chemotherapy to the liver. This "whole organ" therapy is performed by first isolating the circulatory system of the liver, delivering chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body's circulatory system, administer a 30 minute infusion of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect drug-laden blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby minimizing systemic exposure to the drug and related toxic side-effects before the filtered blood is returned to the patient's circulatory system. Through December 31, 2012, the CHEMOSAT/Melblez Kit system has been used on approximately 200 patients through clinical development and early commercial experience in Europe.

Liquidity and Capital Resources

The Company's future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming year. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At December 31, 2012, the Company had cash and cash equivalents totaling $23.7 million, as compared to cash, cash equivalents and certificates of deposit totaling $30.8 million at December 31, 2011. During the twelve months ended December 31, 2012, the Company used $50.0 million of cash in its operating activities, which compares to $37.4 million used for operating activities during the comparable twelve month period in 2011. The increase of $12.6 million is primarily driven by NDA submission related costs, expenses related to the Company's ongoing commercialization efforts in Europe, an increase in compensation related expenses as the Company grew from 80 employees at December 31, 2011 to 92 employees at December 31, 2012, and research and development activities, such as the recently approved melphalan generation two and doxorubicin filters. The Company believes it has access to sufficient capital to fund operating activities for the next twelve months. Assuming Delcath receives FDA approval in 2013, the Company anticipates additional resources will be required to support full U.S. commercialization.

Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fully commercialize the product or to fund development efforts relating to additional indications. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, the Company's assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, public offerings in 2000, 2003, 2009, 2010, 2011 and 2012, registered direct offerings in 2007 and 2009, and an "at the market" equity offering program initiated in 2012. For a detailed discussion of the Company's various sales of securities and the "at the market" equity offering program see Note 8 to the Company's audited financial statements contained in this Annual Report on Form 10-K.

As of December 31, 2012, the Company had two active registration statements. The Company used registration statement 333-165677 for its August 2010 and July 2011 public offerings and for establishing an "at the market" equity offering program detailed in Note 8 to the Company's audited financial statements contained in this Annual Report on Form 10-K. As of December 31, 2012, Delcath had approximately $21.5 million available under this registration statement and intends to use this for its "at the market" equity offering program.

In December 2011, the Company filed a registration statement on Form S-3 with the SEC, which allowed the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deemed prudent or necessary to raise capital at a later date. The registration statement became effective on February 13, 2012 (333-178819). The Company used this registration statement for its May 2012 public offering detailed in Note 8 to the Company's audited financial statements contained in this Annual Report on Form 10-K. The Company subsequently filed a new shelf registration statement on Form S-3 with the SEC which became effective on October 9, 2012 (333-183675). This new shelf replaces the shelf registration filed in December 2011 and allows the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company used this registration statement for its Common Stock Purchase Agreement with Terrapin Opportunity, L.P. detailed in Note 8 to the Company's audited financial statements contained in this Annual Report on Form 10-K. As of December 31, 2012, Delcath had approximately $97.8 million available under this registration statement, of which approximately $6.8 million is reserved for the potential issuance of shares upon the exercise of warrants.

The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of its products, funding of clinical trials, capital expenditures and working capital.

Contractual Obligations, Commercial Commitments and Off-Balance Sheet Arrangements

The Company is obligated to make future payments under various operating lease agreements. The following table provides a summary of significant contractual obligations at December 31, 2012 (in millions):

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Activities:					
Operating Leases	$ 11.2	$ 1.4	$ 4.1	$ 4.0	$ 1.7

Our operating lease obligations at December 31, 2012 include: the annual rent under the lease for our office space at 810 Seventh Avenue, New York, New York, which will expire in March 2021; the annual rent under the leases for our facilities in Queensbury, New York, which expire in July 2014 and June 2015.; and the annual rent for our facility in Galway, Ireland, which will expire in August 2021. See Part I, Item 2, “Properties” and Note 10 to the Company’s audited financial statements contained in this Annual Report on Form 10-K.

Future Capital Needs; Additional Future Funding

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve consistent profitability. The Company believes that it has access to adequate resources to fund operations through 2013 and anticipates that additional working capital may be required to continue our operations. There can be no assurance that such working capital will be available on acceptable terms, if at all.

Results of Operations for the Year Ended December 31, 2012; Comparisons of Results of the Years Ended December 31, 2011 and 2010

Revenue

The Company recorded the first sales of its CHEMOSAT (Hepatic) System in Europe during the year ended December 31, 2012, resulting in revenue of $0.4 million, of which approximately $30,000 is deferred until the Company fulfills its obligations under the distribution agreement and the distributor is able to ship kits to the centers it anticipates servicing.

Cost of Goods Sold

As discussed in Note 4 to the Company’s audited financial statements contained in this Annual Report on Form 10-K, the Company did not recognize any cost of goods sold associated with the revenue or deferred revenue reported in the second or third quarters of 2012 because a portion of the Company’s inventory was purchased prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, including components used in the kits sold during those periods.

During the year ended December 31, 2012, the Company recognized cost of goods sold of approximately $39,000 related to kits that are associated with revenue of $0.4 million. Cost of goods sold of approximately $21,000 is associated with the $30,000 of deferred revenue, resulting in $9,000 deferred net revenue.

As Delcath continues to expand its commercialization in Europe and other parts of the world, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several years. This volatility will be related to several factors, including: the expected use of third party distributors, whose purchase prices will be lower than direct to end user customer prices; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and an improvement in efficiencies as the Company increases its production of the CHEMOSAT system.

Operating Expenses

Selling, General and Administrative Expenses

For the year ended December 31, 2012, selling, general and administrative expenses increased to $28.0 million from $21.3 million for the year ended December 31, 2011. A significant portion of the increase is related to the Company’s expansion, particularly as Delcath has continued executing on its commercialization plans by hiring staff for sales and support positions across Europe. This has led to an increase in personnel-related expenses, as well as all other expenses related to maintaining an office and supporting employees.

For the year ended December 31, 2011, general and administrative expenses increased to $21.3 million from $13.2 million for the year ended December 31, 2010. The Company was continuing its transition from a development stage company to a commercial enterprise with staff dedicated to commercializing the CHEMOSAT/Melblez Kit system. The increase in the Company’s general and administrative expenses corresponded with the initiation of our European commercialization efforts, as well as an increase in staffing in both the United States and Europe.

Research and Development Expenses

For the year ended December 31, 2012, research and development expenses increased to $26.2 million from $25.2 million for the year ended December 31, 2011. The increase in expenses is primarily related to the training and deployment of third party medical science liaisons in Europe, which was partially offset by a reduction in expenses related to the preparation of the NDA submission and a reduction in material-related expenses that are now accounted for as inventory and, as a result, are capitalized rather than expensed.

For the year ended December 31, 2011, research and development expenses increased to $25.2 million from $17.6 million for the year ended December 31, 2010. The increase in expenses was primarily related to our expanded research and development activities, including work on our Generation 2 filter and regulatory expenses related to our submission to the FDA.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the year ended December 31, 2012, the Company had interest income of $19,358 as compared to interest income of $5,249 for the same period in 2011. For the year ended December 31, 2012, the Company invested their cash in interest bearing accounts which yielded higher returns than in 2011.

For the year ended December 31, 2011, the Company had interest income of $5,249 as compared to interest income of $10,698 for the same period in 2010. For the year ended December 31, 2010, the Company earned interest from certificates of deposit which matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the year ended December 31, 2011.

Other Expense and Interest Expense

Other expense is primarily related to currency gains and losses. Interest expense is related to the commitment fee paid upon entering into a Loan and Security Agreement with Silicon Valley Bank (SVB) and an ongoing Revolving Line Facility Fee as required by the agreement with SVB as discussed in Note 9 to the Company's audited financial statements contained in this Annual Report on Form 10-K.

Net Loss

The Company had a net loss for the year ended December 31, 2012, of $51.9 million, an increase of $21.0 million, or 67.9%, compared to the net loss from continuing operations for the same period in 2011. This increase is primarily due to a $13.4 million decrease in the change in the fair value of the warrant liability, which is a non-cash expense, and a $7.7 million increase in operating expenses. The increase in operating expenses reflects a significant increase in costs related to our efforts to commercialize the CHEMOSAT/Melblez Kit system, particularly hiring staff for sales and support positions across Europe and the related expenses to maintain an office and support employees' efforts across Europe.

The Company had a net loss for the year ended December 31, 2011, of $30.9 million, a decrease of $15.8 million, or 33.8%, compared to the net loss from continuing operations for the same period in 2010. This decrease was primarily due to a $31.5 million increase in the change in the fair value of the warrant liability, a non-cash gain, which was offset by a $15.7 million increase in total operating costs. The increase in operating expenses reflected a significant increase in costs related to our preparations to commercialize the CHEMOSAT/Melblez Kit system, expenses related to our additional safety data collection efforts to prepare our submission to the FDA, and an increase in compensation related expenses as the Company grew from 47 to 80 employees during 2011. The warrants issued in 2007 and 2009 as part of our sales of common stock are considered to be derivatives and are subject to valuation and adjustment on a quarterly basis (see item 7A, below for a complete description). This mark-to-market adjustment of the warrant valuation resulted in the recording of $15.6 million in derivative instrument *income* for the year ended December 31, 2011; a $31.5 million difference from the $16.0 million of derivative instrument *expense* recorded in the year ended December 31, 2010.

Application of Critical Accounting Policies

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's audited financial statements contained in this Annual Report on Form 10-K. During 2012, Delcath transitioned from a development stage company to a commercialization organization. At this early commercial stage, the Company has limited choices among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the CHEMOSAT/Melblez Kit system as well as its research and development activities, the cost of which is required to be charged to expense as incurred. This further limits the Company's choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying ASC 740 management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 7 to the Company's audited financial statements contained in this Annual Report on Form 10-K for assets and liabilities the Company has evaluated under ASC 820.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the interest earned on its cash balances.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

In May 2012, the Company completed the sale of 15,333,340 shares of its common stock and the issuance of warrants to purchase 4,600,002 common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. The fair value of the 2012 Warrants on May 31, 2012 was determined by using an option pricing model assuming a risk free interest rate of 0.35%, volatility of 80.64% and an expected life equal to the contractual life of the 2012 Warrants (May 2015). As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At December 31, 2012, the 2012 Warrants were exercisable at $1.20 per share with 4,599,102 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the warrant liability. The fair value of the 2009 Warrants on June 15, 2009 was determined by using an option pricing model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the 2009 Warrants (June 2014). As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's December 2012 sale of common stock. At December 31, 2012, the 2009 Warrants were exercisable at $1.20 per share with 1,043,478 shares outstanding. The 2009 Warrants have a five-year term.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of the total proceeds to the 2007 Warrants. Following the Company's May 31, 2012 sale of common stock and warrants, the 2007 Warrants were exercisable at $1.49 per share with 3,392,592 warrants outstanding. The 2007 Warrants expired on September 21, 2012. Approximately 3.0 million warrants were exercised during the quarter ended September 30, 2012. The remaining liability after the warrant exercises was credited to pre-tax derivative instrument income.

The $3.4 million in proceeds allocated to the 2012 Warrants and the $2.2 million in proceeds allocated to the 2009 Warrants are classified as derivative instrument liabilities. The terms of the warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the twelve month period ended December 31, 2012, the Company recorded pre-tax derivative instrument income of $2.2 million. The resulting derivative instrument liabilities totaled $3.4 million at December 31, 2012. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2012 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	86.08 %	87.14 %
Risk-free interest rates	0.30 %	0.20 %
Expected life (in years)	2.4	1.4

Item 8. Consolidated Financial Statements

Consolidated Financial Statements:

Report of Ernst & Young LLP - Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets at December 31, 2012 and 2011	F-2
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011, and 2010	F-3
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011, and 2010	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010	F-5
Notes to Consolidated Financial Statements	F-6 – F-19

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Delcath Systems, Inc.

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc., as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 consolidated financial position of Delcath Systems, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Delcath Systems, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Metro Park, NJ
March 13, 2013

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets as of December 31, 2012 and 2011
(in thousands, except share data)

	December 31, 2012	December 31, 2011
Assets:		
Current assets		
Cash and cash equivalents	$ 23,726	$ 25,777
Investments – Certificates of deposit	-	4,980
Accounts receivables	144	-
Inventories	1,105	-
Prepaid expenses and other current assets	1,457	1,231
Total current assets	26,432	31,988
Property, plant and equipment, net	4,042	3,253
Total assets	$ 30,474	$ 35,241
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 939	$ 925
Accrued expenses	5,790	5,473
Warrant liability	3,427	2,439
Total current liabilities	10,156	8,837
Deferred revenue	309	300
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2012 and 2011	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 76,849,033 and 48,237,630 shares issued and 76,820,933 and 48,209,530 outstanding at December 31, 2012 and December 31, 2011, respectively	768	482
Additional paid-in capital	218,063	172,613
Accumulated deficit	(198,808)	(146,940)
Treasury stock, at cost; 28,100 shares at December 31, 2012 and December 31, 2011	(51)	(51)
Accumulated other comprehensive income	37	–
Total stockholders' equity	20,009	26,104
Total liabilities and stockholders' equity	$ 30,474	$ 35,241

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Comprehensive Loss
for the Years Ended December 31, 2012, 2011 and 2010
(in thousands, except share and per share data)

	Year ended December 31,		
	2012	**2011**	**2010**
Revenue	$ 346	$ —	$ —
Costs of goods sold	(39)	—	—
Gross profit	307	—	—
Operating expenses			
Selling, general and administrative	$ 27,963	$ 21,283	$ 13,187
Research and development	26,215	25,173	17,556
Total operating expenses	54,178	46,456	30,743
Operating loss	(53,871)	(46,456)	(30,743)
Change in fair value of warrant liability, net	2,159	15,566	(15,951)
Interest income	19	5	10
Other expense and interest expense	(175)	—	—
Net Loss	$ (51,868)	$ (30,885)	$ (46,684)
Common Share data:			
Basic and diluted loss per share	$ (0.85)	$ (0.68)	$ (1.20)
Weighted average number of basic and diluted common shares outstanding	61,275,527	45,236,921	38,991,481
Other comprehensive income (loss):			
Foreign currency translation adjustments	$ 37	$ —	$ —
Unrealized loss on securities	—	26	(10)
Other comprehensive income (loss), total	37	26	(10)
Comprehensive loss	$ (51,831)	$ (30,859)	$ (46,694)

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Stockholders' Equity
for the Years Ended December 31, 2012, 2011 and 2010
(in thousands, except share data)

	Common Stock Issued $0.01 Par Value		In Treasury					
	# of Shares	Amount	# of Shares	Amount	Additional Paid-in Capital	Accumulated deficit	Accumulated Other Comprehensive (loss) income	Total Stockholders' Equity
Balance at December 31, 2009	36,223,097	$ 362	(28,100)	$ (51)	$ 92,835	$ (69,371)	$ (16)	$ 23,759
Compensation expense for issuance of stock options	-	-	-	-	3,839	-	-	3,839
Compensation expense for issuance of restricted stock	414,042	4	-	-	1,671	-	-	1,675
Exercise of warrants and options, common stock surrendered upon restricted stock vesting	1,206,007	12	-	-	3,830	-	-	3,842
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	-	-	-	-	9,154	-	-	9,154
Sale of common stock, net of expenses	5,185,000	52	-	-	33,454	-	-	33,506
Change in unrealized loss on investments	-	-	-	-	-	-	(10)	(10)
Net loss	-	-	-	-	-	(46,684)	-	(46,684)
Balance at December 31, 2010	43,028,146	$ 430	(28,100)	$ (51)	$ 144,783	$ (116,055)	$ (26)	$ 29,081
Compensation expense for issuance of stock options	-	-	-	-	3,605	-	-	3,605
Compensation expense for issuance of restricted stock	173,212	2	-	-	652	-	-	654
Exercise of options, common stock surrendered upon restricted stock vesting	36,272	-	-	-	82	-	-	82
Sale of common stock, net of expenses	5,000,000	50	-	-	23,491	-	-	23,541
Change in unrealized loss on investments	-	-	-	-	-	-	26	26
Net loss	-	-	-	-	-	(30,885)	-	(30,885)
Balance at December 31, 2011	48,237,630	$ 482	(28,100)	$ (51)	$ 172,613	$ (146,940)	$ -	$ 26,104
Compensation expense for issuance of stock options	-	-	-	-	2,807	-	-	2,807
Compensation expense for issuance of restricted stock	408,687	4	-	-	1,014	-	-	1,018
Sale of common stock, net of expenses	25,227,259	252	-	-	36,995	-	-	37,247
Exercise of warrants	2,975,457	30	-	-	4,404	-	-	4,434
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	-	-	-	-	908	-	-	908
Fair value of warrants issued classified as liability	-	-	-	-	(678)	-	-	(678)
Foreign currency translation	-	-	-	-	-	-	37	37
Net loss	-	-	-	-	-	(51,868)	-	(51,868)
Balance at December 31, 2012	76,849,033	$ 768	(28,100)	$ (51)	$ 218,063	$ (198,808)	$ 37	$ 20,009

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows
for the Years Ended December 31, 2012, 2011, and 2010 and
(in thousands)

	Year ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	$ (51,868)	$ (30,885)	$ (46,684)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	2,807	3,605	3,839
Restricted stock and warrant compensation expense	1,018	654	1,675
Depreciation expense	1,331	1,035	472
Loss on disposal of equipment	—	—	7
Warrant liability fair value adjustment	(2,159)	(15,566)	15,951
Non-cash interest income	2	—	(3)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other current assets	(228)	553	(1,001)
Decrease in investment in common stock	—	26	10
Decrease (increase) in accounts receivable	(144)	—	—
Decrease (increase) in inventories	(1,105)	—	—
Increase (decrease) in accounts payable and accrued expenses	331	3,206	1,351
Deferred revenue	9	—	300
Net cash used in operating activities	(50,006)	(37,372)	(24,083)
Cash flows from investing activities:			
Purchase of property, plant, and equipment	(2,120)	(2,607)	(1,638)
Purchase of short-term investments and marketable equity securities	—	(4,980)	(3,235)
Proceeds from maturities of short-term investments	4,980	1,492	1,743
Net cash (used in) provided by investing activities	2,860	(6,095)	(3,130)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	45,058	23,623	37,348
Net cash provided by financing activities	45,058	23,623	37,348
Foreign currency effects on cash	37	—	—
(Decrease) increase in cash and cash equivalents	(2,051)	(19,844)	10,135
Cash and cash equivalents at beginning of period	25,777	45,621	35,486
Cash and cash equivalents at end of period	$ 23,726	$ 25,777	$ 45,621
Supplemental non-cash activities:			
Cashless exercise of stock options and shares surrendered upon restricted stock vesting	$ —	$ (61)	$ 700
Fair value of warrants issued	$ 4,055	$ —	$ —
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$ 908	$ —	$ 9,154

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

(1) Description of Business

We are a specialty pharmaceutical and medical device company focused on oncology. Our proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our initial focus is on the treatment of primary and metastatic liver cancers. We believe that the proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, we announced that our randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. We have also completed a multi-arm Phase 2 trial to treat other liver cancers.

Outside of the United States, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe. In October 2012, we satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT System for Doxorubicin).

In the United States, our proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). We submitted our New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and are seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver. Our NDA was accepted for filing by the FDA on October 15, 2012 and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013.

The CHEMOSAT/Melblez Kit system administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by first isolating the circulatory system of the liver, deliver chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, administer a 30 minute infusion of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect drug-laden blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby minimizing systemic exposure to the drug and related toxic side-effects before the filtered blood is returned to the patient’s circulatory system. Through December 31, 2012, the CHEMOSAT/Melblez Kit system has been used on approximately 200 patients through clinical development and early commercial experience in Europe.

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations through 2013, but anticipates that additional working capital may be required to continue operations. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Condensed Consolidated Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles in the United States of America (GAAP). The preparation of consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company’s consolidated financial statements. The consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

(3) Summary of Significant Accounting Policies

Use of Estimates
The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's condensed consolidated balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, income taxes and operating expense accruals. 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.

Cash Equivalents and Concentrations of Credit Risk
The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Investments
Management determines the appropriate classification of securities at the time of purchase and reevaluates such classification as of each balance sheet date. The Company's securities are classified as either available-for-sale or held-to-maturity. Investments classified as held-to-maturity are stated at amortized cost. Investments classified as available-for-sale are stated at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity.

Accounts Receivable
Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. As the Company's commercial activities expand, collections and payments from customers will be monitored and a provision for estimated credit losses will be created based upon historical experience and specific customer collection issues that may be identified. At December 31, 2012 there were no accounts receivable determined to be uncollectable.

Inventories
Inventories are valued at the lower of cost or market value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory. As of December 31, 2012, there are no reserves for expired, obsolete, or slow-moving inventory.

Prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of December 31, 2012 includes finished goods and components relating to Generation Two of the Delcath Hepatic CHEMOSAT® Delivery System that have been purchased since April 2012. Therefore, as is common for companies transitioning from the development stage to commercial, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company's cost of goods sold will be adjusted accordingly.

Property, Plant and Equipment
Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Derivative Instrument Liability
The Company accounts for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2012 and 2011, the Company did not have any derivative instruments that were designated as hedges.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

Fair Value Measurements
The Company adopted ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.
- Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Deferred Revenue
Deferred revenue on the accompanying consolidated balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. and payment received for product sales to a distributor. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied and will recognize the deferred revenue related to the research and distribution agreement once the milestones are satisfied or over the expected obligation period of the agreement once this amount is reasonably determinable.

Revenue Recognition
Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Selling, General and Administrative
Selling, general and administrative costs include personnel costs and related expenses for the Company's sales, marketing, general management and administrative staff, recruitment, costs related to the Company's commercialization efforts in Europe, professional service fees, professional license, business development and certain general legal activities.

Research and Development
Research and development costs include the costs of materials used for R&D and clinical trials, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation
The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company expensed its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath's common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath's stock over the option's expected term, the risk-free interest rate over the option's expected term, and Delcath's expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the ASC 740 "Income Taxes." Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company applies the accounting guidance issued to address the accounting for uncertain tax positions. This guidance clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements as well as provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company's income tax returns were prepared on the cash basis of accounting through December 31, 2008. The Company filed Form 3115, *Application for Change in Method of Accounting*, to change its tax accounting method from cash basis to accrual basis for years beginning after December 31, 2008. 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. See Note 11 for additional information.

Net Loss per Common Share

For the years ended December 31, 2012, 2011, and 2010 potential common shares from the exercise of options and warrants and the unvested shares of restricted stock were excluded from the computation of diluted earnings per share (EPS) because their effects would be antidilutive.

Shares excluded from the computation of diluted EPS:

	2012	2011	2010
Stock options	4,788,887	4,129,749	3,760,650
Unvested restricted shares	501,468	193,532	67,590
Warrants	5,642,580	2,512,934	2,512,934
Total	10,932,935	6,836,215	6,341,174

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of the CHEMOSAT/Melblez Kit system. A single management team that reports to the Chief Executive Officer comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Recently Adopted Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04 which was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05 which provides new guidance on the presentation of comprehensive income. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and instead requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The adoption of this ASU only requires a change in the format of the current presentation. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's consolidated financial statements.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

(4) Inventories

Inventories consist of:

(in thousands)	December 31, 2012	December 31, 2011
Raw materials	$ 197	$ -
Work-in-process	405	-
Finished goods	503	-
Total	$ 1,105	$ -

Delcath transitioned from a development stage company to a commercial organization with operational activities in April 2012. A portion of the Company's inventory was purchased prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, including components used in the kits sold during the twelve months ended December 31, 2012. As a result, some of the costs of sales related to recognized and deferred revenue was expensed in earlier periods.

(5) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	December 31, 2012	December 31, 2011
Leaseholds	$ 1,716	$ 1,148
Furniture	952	880
Equipment	1,473	1,371
Computers	2,141	1,212
Buildings and Land	603	154
	6,885	4,765
Accumulated depreciation	(2,843)	(1,512)
Total	$ 4,042	$ 3,253

Depreciation expense for the years ended December 31, 2012, 2011, and 2010 was $1.3 million, $1.0 million, and $0.5 million, respectively.

(6) Accrued Expenses

Accrued expenses include the following:

(in thousands)	December 31, 2012	December 31, 2011
Compensation, excluding taxes	$ 1,933	$ 1,688
Professional fees	1,437	1,227
Contract Research Organization	1,283	1,800
Other[1]	1,137	758
Total accrued liabilities	$ 5,790	$ 5,473

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2012 and 2011.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

(7) Assets and Liabilities Measured at Fair Value

Derivative Financial Instruments
As disclosed in Note 8, the Company allocated proceeds to the warrants issued in connection with a private placement and recent public offering that were classified as liabilities and accounted for as a derivative instrument in accordance with ASC 815. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The riskless rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

Money Market Funds and Treasury Bills
The Company has determined that the inputs associated with the fair value determination are based on quoted prices (unadjusted) and as a result the investments are classified within Level 1 of the fair value hierarchy.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2012 and 2011, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2012	2011	2012	2011	2012	2011	2012	2011
Assets								
Money market funds	$ 1,967	$ 25,417	—	—	—	—	$ 1,967	$ 25,417
Liabilities								
Derivative instrument liabilities	—	—	—	—	$ 3,427	$ 2,439	$ 3,427	$ 2,439

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Derivative
Balance at December 31, 2009	$ 11,207
Total increase in the liability included in earnings	15,951
Fair value of warrants exercised or expired	(9,153)
Balance at December 31, 2010	$ 18,005
Total change in the fair value of the liability included in earnings	(15,566)
Balance at December 31, 2011	$ 2,439
Total change in the fair value of the liability included in earnings	(2,159)
Fair value of warrants issued	4,055
Fair value of warrants exercised or expired	(908)
Balance at December 31, 2012	$ 3,427

(8) Stockholders' Equity

Stock Issuances
In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of those proceeds to the 2007 Warrants (see below). In accordance with the provisions of the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's May 31, 2012 sale of common stock and warrants and became exercisable at $1.49 per share with 3,392,592 warrants outstanding. The 2007 Warrants expired on September 21, 2012. Approximately 3.0 million warrants were exercised during the quarter ended September 30, 2012. The remaining liability after the warrant exercises was credited to pre-tax derivative instrument income.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants (see below). As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's May 31, 2012 sale of common stock and warrants. At December 31, 2012, the 2009 Warrants were exercisable at $1.20 per share with 1,043,478 warrants outstanding. The 2009 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In August 2010, the Company completed the sale of 5,185,000 shares of its common stock pursuant to an underwriting agreement, raising approximately $33.5 million after expenses. The shares were issued pursuant to an effective registration statement on Form S-3 (333-165677).

In July 2011, the Company completed the sale of 5,000,000 shares of its common stock pursuant to an underwriting agreement, raising approximately $23.5 million after expenses. The shares were issued pursuant to an effective registration statement on Form S-3 (333-165677).

In December 2011, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC to sell shares of the Company's common stock, par value $.01 per share, having aggregate sales proceeds of $39.8 million, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. As of December 31, 2012, the Company had sold approximately 8.1 million shares of its common stock through the program for net proceeds after related expenses of approximately $17.6 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-165677). The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. As of December 31, 2012, there was approximately $21.5 million available under this program.

In May 2012, the Company completed the sale of 15,333,340 shares of its common stock and the issuance of warrants to purchase 4,600,002 common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. At December 31, 2012, the 2012 Warrants were exercisable at $1.20 per share with 4,599,102 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (333-178819).

In December 2012, the Company entered into a Common Stock Purchase Agreement (Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin). The Purchase Agreement provides that Terrapin is committed to purchase up to $35,000,000 of our common stock over the 24-month term of the Purchase Agreement.. As of December 31, 2012, the Company has sold approximately 1.7 million shares of its common stock through the program for net proceeds after related expenses of approximately $1.9 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-183675). The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. As of December 31, 2012, there was approximately $32.9 million available under this program.

Stock Option Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000, and 6,500,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In May 2012, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 2,300,000 shares, from 4,200,000 to 6,500,000 upon a favorable vote by the Company's stockholders. A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Compensation and Stock Option Committee of the board of directors which determines the individuals to whom awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for 2012, 2011, and 2010 is as follows:

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

	Number of Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2009	3,345,000	$ 1.23–6.18	$ 3.72	6.58
Granted	700,650	5.28-15.54	9.81	
Expired	(120,000)	2.78-3.59	3.25	
Forfeited	(25,000)	4.12-6.18	4.81	
Exercised	(140,000)	1.43-6.18	3.52	
Outstanding at December 31, 2010	3,760,650	$ 1.23-15.54	$ 4.88	6.65
Granted	671,326	2.00-9.18	5.72	
Expired	(120,000)	3.28	3.28	
Forfeited	(136,900)	1.40-9.93	4.65	
Exercised	(45,327)	2.44-3.28	3.18	
Outstanding at December 31, 2011	4,129,749	$ 1.23-15.54	$ 5.09	6.38
Granted	1,207,452	1.43-4.60	3.80	
Expired	(420,000)	1.88-5.85	4.81	
Forfeited	(128,314)	2.26-9.18	5.05	
Exercised	-			
Outstanding at December 31, 2012	4,788,887	$ 1.23-15.54	$ 4.79	6.88
Exercisable at December 31, 2012	3,105,535	$ 1.23-15.54	$ 4.85	5.80

The estimated fair value of each option award granted was determined on the date of grant using an option pricing model with the following assumptions for option grants during the years ended December 31, 2012, 2011 and 2010:

	Year Ended December 31,		
	2012	2011	2010
Weighted average risk-free interest rate	1.11%	2.07%	2.54%
Weighted average expected volatility	79.89%	74.64%	73.80%
Expected volatility	77.37-84.81%	73.88% - 79.11%	72.16% - 75.40%
Dividend yield	0.00%	0.00%	0.00%
Weighted average expected option term (in years)	6.17	6.00	5.87
Weighted average grant date fair value	$ 2.59	$ 3.79	$ 6.30

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life of the stock options on the grant date. The expected option term for grants made during the second half of 2012 is based on actual historical results. The expected option term for grants made prior to that was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under ASC 718. This method of determining the expected holding period was utilized because the Company did not have sufficient historical experience from which to estimate the period.

A summary of the Company's non-vested options to purchase shares as of December 31, 2012 and changes during the twelve months ended December 31, 2012 and December 31, 2011 are presented below:

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

	Non-Vested Options	
	Number of Options	Weighted Average Exercise Price
Non-vested at December 31, 2010	1,362,316	$ 6.39
Granted	670,826	5.72
Vested	(812,874)	5.60
Forfeited	(61,900)	8.58
Non-vested at December 31, 2011	1,158,368	$ 6.44
Granted	1,207,452	3.80
Vested	(570,518)	6.38
Forfeited	(111,950)	4.79
Non-vested at December 31, 2012	1,683,352	$ 4.68

Compensation expense recognized relating to stock options granted to employees (in millions):

	2012	2011	2010
Selling, general and administrative	$ 1.7	$ 2.2	$ 2.5
Research and development	1.1	1.4	1.1
Total	$ 2.8	$ 3.6	$ 3.6

Additional compensation expense of $2.0 million, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 1.4 years.

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2012 is $0. The aggregate intrinsic value represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price of $1.23 as of December 31, 2012, which would have been received by the option holders had those option holders exercised their options as of that date.

A summary of the Company's restricted stock activity as of December 31, 2012 and changes during the twelve months ended December 31, 2012 and December 31, 2011 are presented below:

	Restricted Stock Activity	
	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2010	67,590	$ 6.71
Granted	188,277	5.67
Vested	(47,270)	5.62
Forfeited	(15,065)	8.35
Non-vested at December 31, 2011	193,532	$ 5.84
Granted	429,720	2.83
Vested	(100,751)	6.18
Forfeited	(21,033)	4.39
Non-vested at December 31, 2012	501,468	$ 3.26

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

Compensation expense recognized relating to restricted stock granted to employees (in millions):

	2012	2011	2010
Selling, general and administrative	$ 0.7	$ 0.5	$ 0.8
Research and development	0.3	0.1	0.8
Total	$ 1.0	$ 0.6	$ 1.6

Additional compensation expense of $0.7 million relating to the unvested portion of restricted stock granted, is expected to be recognized over a remaining average period of 1.2 years.

Warrants

The Company allocated part of the proceeds of a private placement in 2007 and public offerings in 2009 and 2012 of the Company's common stock to warrants issued in connection with those transactions. The Company determined that these warrants should be classified as liabilities rather than equity as the terms of the warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As of December 31, 2012, the 2009 and 2012 Warrants are classified as derivative instrument liabilities. The 2007 Warrants were exercised or expired in September 2012 and are no longer part of the warrant liability on the balance sheet.

The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820-10-35. There are six inputs: the closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on our historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10-35-40). The riskless rate of return is a Level 2 input as defined in ASC 820-10-35-48, while the historical volatility is a Level 3 input as defined in ASC 820-10-55-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

For the year ended December 31, 2012, the Company recorded pre-tax derivative instrument income of $2.2 million. The resulting derivative instrument liabilities totaled $3.4 million at December 31, 2012. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2012 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	86.08 %	87.14 %
Risk-free interest rates	0.30 %	0.20 %
Expected life (in years)	2.4	1.4

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

A summary of warrant activity is as follows:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2009	3,746,184	$ 3.44–3.91	$ 3.52	3.08
Issued	–			
Exercised	(1,159,000)	3.44–3.91	3.52	
Expired	(74,250)	3.91	3.91	
Outstanding at December 31, 2010	2,512,934	$ 3.44-3.60	$ 3.51	2.45
Issued	–			
Exercised	–			
Expired	–			
Outstanding at December 31, 2011	2,512,934	$ 3.44-3.60	$ 3.51	1.45
Issued	6,523,120	1.49-3.03	1.65	
Exercised	(2,975,457)	1.49-1.65	1.49	
Expired	(418,017)	1.49	1.49	
Outstanding at December 31, 2012	5,642,580	$ 1.20	$ 1.20	2.24

(9) Loan and Security Agreement

In April 2012, the Company entered into a four-year Loan and Security Agreement (the "Credit Agreement") with Silicon Valley Bank ("SVB"), as lender. The Credit Agreement consists of a revolving credit facility in an amount equal to the lesser of $20,000,000 and the Company's Borrowing Base (as defined in the Credit Agreement). In order to draw down on the facility, the Company will need to have at least the greater of (i) $15,000,000 in cash and cash equivalents in its account with SVB plus the amount of all outstanding obligations of the Company owed to SVB and (ii) trailing 3 months Cash Burn (as defined in the Credit Agreement) plus the amount of all outstanding obligations of the Company owed to SVB. At December 31, 2012, the Company had not used any of the available funds.

(10) Commitments

Operating Leases

In February 2010, the Company entered into an agreement to lease (Initial Lease) 8,629 square feet of office space in New York, New York with an option to expand an additional 8,629 square feet. The term of the Initial Lease began in March, 2010 and provides for total annual base rental payments of $457,337 during years 1-3 and the first half of year 4 of the Initial Lease term, and of $491,853 during the second half of year 4 and years 5-7 of the Lease term. The Initial Lease also requires the Company to pay customary building operating expenses and a pro-rata share of real estate taxes.

In September 2010, the Company exercised its option right under the Initial Lease and entered into an agreement to lease (Lease Amendment) an additional 8,629 square feet of office space in New York, New York. The term of the Lease Amendment began in January 2011 and will expire in March 2021. In addition, the Lease Amendment extends the term of the Initial Lease to March 2021. The Lease Amendment provides for annual base rent of $504,078 for years 1-5 and of $547,533 for years 6-11 of the Lease Amendment term. In addition, the Lease Amendment provides for total base rent on the space leased under the Initial Lease of $543,627 for the extended term of November 2017 – March 2021. Combined, the Initial Lease and the Lease Amendment provide for annual rent of $961,000 in 2012, $970,000 in 2013, $996,000 in 2014 and 2015, $1.0 million in 2016, and $1.1 million in 2017-2020.

In July 2012, the Company entered into a lease agreement for 95-97 Park Road in Queensbury, NY, agreeing to lease the 6,000 square feet at that location. The term began on July 18, 2012 and is effective for a one year period with an option to extend the lease for an additional year. The agreement provides for total annual base rent of $42,000.

In August 2011, Delcath Systems Limited entered into an agreement of lease for an office and manufacturing facility located in the city of Galway, Ireland. This facility is approximately 19,200 square feet and is intended to be the location of Delcath's European headquarters. The Lease is for a term of ten years, commencing August 2, 2011; although Delcath Limited has the option to terminate the Lease after the fifth year upon not less than six months notice. The Lease provides for fixed annual lease amounts payable in advance in equal quarterly installments. The annual lease amounts, which escalate annually, are as follows (USD conversions are based on the December 31, 2012 conversion rate): Year 1 – €106,051 ($140,179), Year 2 – €134,974 ($178,410), Year 3 – €159,077 ($210,269) and Years 4 and 5 – €183,179 ($242,127). Annual lease amounts in years 6 through 10 are subject to adjustment based upon the percentage increase in the consumer price index as published by the Ireland Central Statistics Office. Delcath Limited is also required to pay for customary building operating expenses. Delcath Limited's payment obligations and performance of the Lease are guaranteed by Delcath.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

In May 2012, the Company entered into an agreement to purchase 10,320 square feet located at 566 Queensbury Avenue, Queensbury, NY (the "Facility"), which was previously leased. The purchase price for the Facility was $440,000 as stated in the initial lease agreement, which commenced on September 1, 2009.

In June 2012, the Company entered into an agreement to lease 18,000 square feet at Suites 2 and 3 Country Club Road, Queensbury, NY for a three year period. This amends the initial lease at 2 Country Club Road, which commenced on November 12, 2010. The location houses a portion of the Company's research and manufacturing operations. The lease provides for annual base rent of $216,000, as well as the payment of customary building operating expenses and real estate taxes.

Future minimum lease payments under all operating leases at December 31, 2012 are as follows (in thousands):

Year Ended December 31:	Future Lease Payment
2013	$ 1,422
2014	1,460
2015	1,328
2016	1,278
2017	1,294
	$ 6,782

Rent expense totaled approximately $1.5 million, $1.2 million and $0.5 million, for the years ended December 31, 2012, 2011 and 2010, respectively.

Letters of Credit
Under the terms of the lease agreement for office space in New York City, the Company is required to maintain a letter of credit in the amount of $881,297. The letter of credit expires on February 1, 2014 if not renewed by the Company.

(11) Income Taxes

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

	Year Ended December 31,		
(in thousands)	**2012**	**2011**	**2010**
Income taxes using U.S. federal statutory rate	$ (17,621)	$ (10,501)	$ (15,872)
Amoritization of Gain on IP Migration	754	–	–
State income taxes, net of federal benefit	(4,299)	(3,418)	(4,276)
Foreign rate differential	3,716	52	–
Valuation allowance	17,561	20,563	15,041
Derivative charge	(734)	(5,292)	5,423
Stock option exercises and cancellations	310	102	–
Research and development credits	326	(1,633)	(519)
Other	(13)	127	203
Total	$ –	$ –	$ –

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

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

(in thousands)	2012	2011
Deferred tax assets:		
Employee compensation accruals	$ 6,176	$ 4,973
Accrued liabilities	299	283
Research tax credits	2,382	2,708
Other	31	3
Net operating losses	63,765	47,118
Total deferred tax assets	72,653	55,085
Deferred tax liability:		
Total deferred tax liabilities	–	–
Valuation allowance	72,653	55,085
Net deferred tax assets	$ –	$ –

As of December 31, 2012 and December 31, 2011, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $138.1 million and $122.1 million, respectively. A portion of the federal amount, $8.6 million, is subject to an annual limitation of approximately $123,000 as a result of a change in the Company's ownership through May 2003, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitation, approximately $131.9 million is available to offset future federal taxable income which will expire between 2018 and 2032. As of December 31, 2012 and December 31, 2011, the Company had net operating loss carryforwards for state and city income tax purposes of approximately $231.0 million and $180.2 million, respectively, which expire through 2032. As of December 31, 2012 and December 31, 2011, the Company had a net operating loss carryforward for foreign income tax purposes of $17.4 million and $0.2 million, respectively, which have indefinite carryforward periods. There were no foreign net operating losses prior to 2011.

The Company has a tax benefit of approximately $1.0 million related to the exercise of non-qualified stock options. Pursuant to ASC 718, the benefit will be recognized and recorded to additional paid-in capital when the benefit is realized through the reduction of taxes payable. Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company's valuation allowance increased by approximately $17.6 million, $20.5 million, $15.0 million, $5.9 million, and $3.2 million in 2012, 2011, 2010, 2009, and 2008, respectively.

The Company complies with the provisions of ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10.

The Company is subject to income tax in the U.S., the Republic of Ireland, and certain state jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service, international tax authorities, or any states in connection with income taxes. The periods from December 31, 2009 to December 31, 2012 remain open to examination by the U.S. Internal Revenue Service, and international and state tax authorities. The periods from December 31, 2011 to December 31, 2012 remain open to examination by the Republic of Ireland. In addition, federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

Delcath recognizes interest accrued related to unrecognized tax benefits and penalties, if incurred, as a component of income tax expense.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2012, 2011 and 2010

(12) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2012 and 2011.

	2012 Quarters Ended			
(in thousands except per share amounts)	**March 31**	**June 30**	**September 30**	**December 31**
Operating loss	$ (14,554)	$ (15,316)	$ (12,175)	$ (11,825)
Change in fair value of warrant liability, net	(338)	917	446	1,134
Net loss	(14,889)	(14,512)	(11,813)	(10,657)
Basic and diluted loss per share	(0.31)	(0.26)	(0.18)	(0.14)

	2011 Quarters Ended			
(in thousands except per share amounts)	**March 31**	**June 30**	**September 30**	**December 31**
Operating loss	$ (7,814)	$ (10,486)	$ (12,181)	$ (15,974)
Change in fair value of warrant liability, net	5,966	5,027	3,872	702
Net loss	(1,848)	(5,459)	(8,309)	(15,268)
Basic and diluted loss per share	(0.04)	(0.13)	(0.18)	(0.32)

(13) Subsequent Events

During the first quarter through February 28, 2013, the Company sold approximately 14.2 million shares of our common stock under the Sales Agreement through an “at the market” equity offering program for net proceeds of approximately $20.9 million before related expenses. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. There are no proceeds remaining under the program.

Delcath completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no other subsequent events requiring disclosure in or adjustment to these financial statements.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, Delcath's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures as of December 31, 2012 (the end of the period covered by this Annual Report on Form 10-K), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in its reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes to the Company's internal control over financial reporting that occurred during the fourth fiscal quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, its internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Delcath's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Delcath's management assessed the effectiveness of its internal control over financial reporting as of December 31, 2012. In making this assessment, it used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2012, the Company's internal control over financial reporting was effective based on those criteria.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Delcath Systems, Inc.

We have audited Delcath Systems, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Delcath Systems, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Delcath Systems Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Delcath Systems, Inc. as of December 31, 2012 and 2011 and the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of Delcath Systems, Inc. and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Metro Park, New Jersey
March 13, 2013

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Except for the information about our Code of Ethics below, the information required by this Item 10 is incorporated by reference from our definitive proxy statement for our 2013 Annual Meeting of Stockholders (the "Proxy Statement").

We maintain a Code of Business Conduct and Ethics (Code) that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including our independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates our expectations of our employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of our Code is published on our web site at http://delcath.com/investors/governance. We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions on our web site.

Item 11. Executive Compensation.

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required for this Item is incorporated by reference from our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required for this Item is incorporated by reference from our Proxy Statement.

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. ***Consolidated Financial Statements***: The following Consolidated Financial Statements and Supplementary Data of Delcath and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:

Consolidated Balance Sheets at December 31, 2012 and 2011

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011, and 2010

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011, and 2010

Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010

Notes to Consolidated Financial Statements

2. ***Exhibits***: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DELCATH SYSTEMS, INC.

/s/Eamonn P. Hobbs
Eamonn P. Hobbs
President and Chief Executive Officer
(Principal Executive Officer)
Dated: March 13, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/Eamonn P. Hobbs Eamonn P. Hobbs	President and Chief Executive Officer, and Director (Principal Executive Officer)	March 13, 2013
/s/Graham G, Miao Graham G. Miao, Ph.D.	Chief Financial Officer (Principal Financial Officer)	March 13, 2013
/s/Barbra C. Keck Barbra C. Keck	VP, Controller (Principal Accounting Officer)	March 13, 2013
/s/Harold S. Koplewicz Harold S. Koplewicz, M.D.	Chairman of the Board	March 13, 2013
/s/Laura Brege Laura Brege	Director	March 13, 2013
/s/Anastasios Konidaris Anastasios Konidaris	Director	March 13, 2013
/s/Gabriel Leung Gabriel Leung	Director	March 13, 2013
/s/Laura Philips Laura Philips, Ph.D.	Director	March 13, 2013
/s/Roger Stoll Roger Stoll, Ph.D.	Director	March 13, 2013
/s/Douglas Watson Douglas Watson	Director	March 13, 2013

Exhibit Index

Exhibit No.		Description
3.1		Amended and Restated Certificate of Incorporation of the Company, as amended to June 30, 2005 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed June 5, 2006 (Commission File No. 001-16133).
3.2		Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2 (Registration No. 333-39470)).
4.2		Form of Warrant to Purchase Shares of Common Stock dated June 15, 2009 issued pursuant to the Subscription Terms dated as of June 9, 2009 between the Company and Capital Ventures International (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 10, 2009 (Commission File No,. 001-16133)).
4.3		Form of Warrant to Purchase Shares of Common Stock dated May 31, 2012 issued pursuant to the Underwriting Agreement dated as of May 25, 2012 between the Company and Cowen and Company, LLC and Wedbush Securities Inc. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 31, 2012 (Commission File No,. 001-16133)).
10.1	*	2004 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's definitive Proxy Statement dated April 29, 2004 (Commission File No. 001-16133)).
10.2	*	2009 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's definitive Proxy Statement dated April 30, 2009 (Commission File No. 001-16133)).
10.3	*	Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.4	*	Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.5	*	Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2005 (Commission File No. 001-16133)).
10.6	†	Cooperative Research and Development Agreement dated as of March 29, 2007 between the Company and the National Cancer Institute (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009 (Commission File No. 001-16133)).
10.7		Form of Indemnification Agreement dated April 8, 2009 between the Company and members of the Company's Board of Directors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 10, 2009 (Commission File No. 001-16133)).
10.8	*	Separation and General Release Agreement dated as of July 5, 2009 between the Company and Richard L. Taney (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 7, 2009 (Commission File No. 001-16133)).
10.9	*	Employment Agreement dated as of July 1, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 7, 2009 (Commission File No. 001-16133)).
10.10	*	Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.11	*	Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).

10.12	*	Employee Stock Option Grant Letter dated as of September 14, 2009 between the Company and David A. McDonald (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 17, 2009 (Commission File No. 001-16133)).
10.13	*	Employee Stock Option Grant Letter dated October 20, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009 (Commission File No. 001-16133)).
10.14		Lease between SLG 810 Seventh Lessee LLC and the Company dated as of February 5, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 (Commission File No. 001-16133)).
10.15		Research and Distribution Agreement between CHIFU Trading Co Ltd and the Company dated as of February 9, 2010 (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2010 (Commission File No. 001-161233)).
10.16	*	Amendment No. 1 to Form of Employee Stock Option Grant Letter dated as of March 11, 2010 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 (Commission File No. 001-16133)).
10.17	*	Employee Stock Option Grant Letter dated as of March 11, 2010 between the Company and Eamonn P. Hobbs (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 (Commission File No. 001-16133)).
10.18		Amended and Restated Supply Agreement between B. Braun Medical Inc and the Company dated as of May 4, 2010 (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 (Commission File No. 001-16133)).
10.19	*	Employment Agreement dated as of May 5, 2010 between the Company and Barbra Keck (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 11, 2010 (Commission File No. 001-16133)).
10.20		Underwriting Agreement between Canaccord Genuity, Inc. and the Company, dated as of August 16, 2010 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed August 17, 2010 (Commission File No. 001-16133)).
10.21		Lease Modification, Extension and Additional Space Agreement between SLG 810 Seventh Lessee LLC and the Company dated as of September 27, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 30, 2010 (Commission File No. 001-16133)).
10.22	†	License, Supply and Contract Manufacturing Agreement between Synerx Pharma, LLC and Bioniche Teoranta and the Company dated as of October 13, 2010.
10.23	*	Form of Restricted Stock Agreement under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.24		Form of Restricted Stock Agreement (Non-Employee Directors) under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.25		Form of Restricted Stock Agreement (Consultants) under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.26	*	Form of Non-Statutory Stock Option Grant Letter under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.27		Form of Non-Statutory Stock Option Grant Letter (Non-Employee Directors) under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).

10.28		Form of Non-Statutory Stock Option Grant Letter (Consultants) under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.29	*	Interim Agreement, dated July 6, 2011, by and between Delcath Systems, Inc. and Eamonn Hobbs (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 11, 2011 (Commission File No. 001-16133)).
10.30	*	Second Interim Agreement between Delcath Systems, Inc. and Eamonn Hobbs, dated August 8, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 11, 2011 (Commission File No. 001-16133)).
10.31	*	Employment Agreement between Delcath Systems, Inc. and Eamonn Hobbs, dated August 10, 2011 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 11, 2011 (Commission File No. 001-16133)).
10.32	*	Employment Offer Letter between Delcath Systems, Inc. and Graham Miao, Ph.D., dated August 31, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 26, 2011 (Commission File No. 001-16133)).
10.33		Form of Employee Confidentiality and Restrictive Covenant Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 26, 2011 (Commission File No. 001-16133)).
10.34		Lease Agreement, dated August 2, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 (Commission File No. 001-16133)).
10.35		Amendment No. 4 to the Cooperative Research and Development Agreement, dated as of January 28, 2012, between Delcath Systems, Inc. and the National Cancer Institute (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 31, 2012 (Commission File No. 001-16133)).
10.36	*	Employment Agreement between Delcath Systems, Inc. and Peter Graham, dated April 13, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2012 (Commission File No. 001-16133)).
10.37		Underwriting Agreement between Cowen and Company, LLC and Wedbush Securities Inc. and the Company, dated as of May 25, 2012 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed May 31, 2012 (Commission File No. 001-16133)).
10.38		Loan and Security Agreement dated April 20, 2012 between Silicon Valley Bank and Delcath Systems, Inc.[1]
10.39		Employment Offer Letter between Delcath Systems, Inc. and Jennifer Simpson, Ph.D., M.S.N., C.R.N.P., dated March 7, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 26, 2012 (Commission File No. 001-16133))
10.40		Employment Agreement between Delcath Systems, Inc. and Krishna Kandarpa, MD, Ph.D., dated July 16, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 19, 2012 (Commission File No. 001-16133))
10.41		Common Stock Purchase Agreement between Delcath Systems, Inc. and Terrapin Opportunity, L.P. dated December 5, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 5, 2012 (Commission File No. 001-16133))
10.42		First Amendment to Research and Distribution Agreement between Delcath Systems, Inc. and CHI-FU Trading Co., Ltd., dated January 26, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 30, 2013 (Commission File No. 001-16133))
10.43		Amendment No.1 to Common Stock Purchase Agreement between Delcath Systems, Inc. and Terrapin Opportunity, L.P. dated March 6, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 7, 2013 (Commission File No. 001-16133))
23.1	**	Consent of Ernst & Young LLP
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

* Indicates management contract or compensatory plan or arrangement.

** Filed herewith.

1 (incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012).

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-183675) of Delcath Systems, Inc., and
(2) Registration Statement (Form S-8 No. 333-182014) pertaining to the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan of Delcath Systems, Inc.;

of our reports dated March 13, 2013, with respect to the consolidated financial statements of Delcath Systems, Inc. and the effectiveness of internal control over financial reporting of Delcath Systems, Inc. included in this Annual Report (Form 10-K) of Delcath Systems, Inc. for the year ended December 31, 2012.

/s/ Ernst & Young LLP
Metro Park, New Jersey
March 13, 2013

EXHIBIT 31.1

Certification
of Principal Executive Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Eamonn P. Hobbs, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;

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

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

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

DATE
March 13, 2013

/s/Eamonn P. Hobbs
Eamonn P. Hobbs
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification
of Principal Financial Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Graham G. Miao, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;

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

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

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

DATE
March 13, 2013

/s/Graham G. Miao
Graham G. Miao, Ph.D.
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eamonn P. Hobbs, the Chief Executive Officer and President of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

DATE
March 13, 2013

/s/Eamonn P. Hobbs
Eamonn P. Hobbs
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Graham G. Miao, the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

DATE
March 13, 2013

/s/Graham G. Miao
Graham G. Miao, Ph.D.
Chief Financial Officer
(Principal Financial Officer)