DELCATH SYSTEMS, INC.
Form 10-K
March 12, 2014

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, 2013

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 (State or other jurisdiction of incorporation or organization)	06-1245881 (I.R.S. Employer Identification No.)
810 Seventh Avenue, 35th Floor, New York, NY (Address of principal executive offices)	10019 (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 o
Non-accelerated filer x (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 $0.37 per share, was $35,514,410 as of June 30, 2013.

At March 12, 2014, the registrant had outstanding 150,711,442 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2014 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.

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DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the period ended December 31, 2013 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," 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, 2013 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, 2013 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, 2013 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 commencement of future clinical trials and the results and timing of those clinical trials;
- 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 CHEMOSAT/Melphalan HDS system and enter into supplier contracts;
- our ability to successfully manufacture the CHEMOSAT/Melphalan HDS system;
- our ability to successfully commercialize the CHEMOSAT/Melphalan HDS system and successfully obtain reimbursement;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- 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

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan HDS)—is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic

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 for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe.

In the United States, the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States.

About CHEMOSAT/Melphalan HDS

The CHEMOSAT/Melphalan HDS system administers 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, known as percutaneous hepatic perfusion (PHP), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug, and related toxic side-effects, before the filtered blood is returned to the patient’s circulatory system.

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The CHEMOSAT/Melphalan HDS 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.

We believe the CHEMOSAT/Melphalan HDS 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 in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (United Kingdom and Germany) where the prospect of securing adequate reimbursement for the procedure is strongest. In other EU markets, such as Spain, Italy, France and The Netherlands, we continue to focus our efforts on clinical awareness and adoption. Concurrently, we are initiating a phased Clinical Development Program for the CHEMOSAT/Melphalan HDS system in hepatocellular carcinoma, or primary liver cancer (HCC).

Treatment with the CHEMOSAT/Melphalan HDS

Currently there are few effective treatment options for cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. The most advanced application for which the CHEMOSAT/Melphalan HDS system was evaluated is for the treatment of metastatic melanoma in the liver. During the Company's 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/Melphalan HDS system. Treatment with the CHEMOSAT/Melphalan HDS system is a repeatable procedure, and during clinical trials patients received an average of three procedures at approximately four to eight week intervals. A new disposable CHEMOSAT/Melphalan HDS system is used for each treatment.

Risks associated with the CHEMOSAT/Melphalan HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/Melphalan HDS system is associated with toxic side-effects and certain risks, some of which are potentially life-threatening. In clinical trials using early versions of the Melphalan HDS system, the integrated safety population of patients treated with early versions of the CHEMOSAT/Melphalan HDS system showed these risks to include: a 4.1% incidence of deaths due to adverse reactions; 4% incidence of stroke; 2% incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment; a ≥ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week; and 8% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation. Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments. The trials that comprised this integrated safety population used early versions of the CHEMOSAT/Melphalan HDS system, including the Generation One filter, and did not include use of the Generation Two filter. The Company believes that the risks associated with the procedure are manageable.

Development History

Our Phase 3 clinical trial and our multi-arm Phase 2 clinical trial of the CHEMOSAT/Melphalan HDS 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 Melphalan HDS 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 eight 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.

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On April 21, 2010, the Company announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan HDS 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 Multi-Histology, Unresectable Hepatic Tumor Trial

In addition to the Phase 3 metastatic melanoma clinical trial, in 2010 the Company also concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using the Melphalan HDS system in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), 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 HCC cohort (n=8), a positive signal in hepatic malignancies was observed in 5 patients. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hepatic progression free survival (hPFS) ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. 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.

Regulatory History

In the United States, the Melphalan HDS system is subject to regulation as a combination product composed of both a drug product and device product. In August 2012, the Company submitted its New Drug Application (NDA) under Section 505(b)(2) of the Federal Food and Drug Cosmetic Act (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 for the product under the proposed trade name Melblez™ Kit. The Company subsequently amended the indication it was seeking to ocular melanoma metastatic to the liver. The Company's NDA was accepted for filing by the FDA on October 15, 2012 with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013.

On February 27, 2013 the Company announced that the FDA's Oncologic Drugs Advisory Committee (ODAC) would review its NDA on May 2, 2013. On March 18, 2013 the Company supplied certain information in response to an FDA request. Subsequently, on April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

ODAC

On May 2, 2013 the Company announced that the ODAC panel voted 16 to 0, with no abstentions, that the benefits of treatment with the Melblez Kit do not outweigh the risks associated with the procedure using the early clinical trial versions of the system.

A brief summary of the issues discussed at the ODAC is as follows:

Procedure-related deaths

A significant portion of FDA's presentation to the ODAC panel was focused on the FDA's assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. Five deaths (4.1%) in the Phase 2 and Phase 3 clinical trials were considered by the treating principal investigators to be treatment-related

and resulted from adverse events. Four of these deaths were in the Phase 3 trial and one in the Phase 2 trial. The treatment-related deaths in the pooled PHP population were a consequence of either the PHP procedure; or the direct local effects of melphalan during the procedure, or both.

- Two deaths due to gastric ulceration/perforation:
  - A death due to upper GI hemorrhage in the Phase 2 trial was in a male patient with pancreatic neuroendocrine tumor (NET) who had a prior surgical procedure (referred to as a Whipple's procedure) and consequent abnormal architecture of the upper GI tract, its vasculature, and biliary tree. This patient died on Day 74 after melphalan/PHP treatment and an autopsy revealed a ruptured right hepatic artery as the primary cause of death.
  - Subsequent to this patient's death, a protocol amendment was implemented that excluded patients with prior Whipple's procedure from being treated.

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- A death due to gastric perforation occurred in a male patient in the Phase 3 trial who crossed over to melphalan/PHP treatment after hepatic progression on best alternative care (BAC). This patient went into cardiopulmonary arrest and died during a laparotomy on Day 18 after his second treatment cycle. An autopsy revealed two gastric ulcers which likely resulted from the infusion of melphalan during a hepatic artery spasm with consequent misperfusion into the GI vasculature.
- Subsequent to this patient's death, a protocol amendment addressed the need to embolize collateral circulation and to check for vasospasm prior to the administration of melphalan. If spasm is present, the use of intra-arterial nitroglycerin should be used to alleviate the spasm prior to the administration of melphalan. No further deaths occurred related to gastric ulceration/perforation after the amendment was put into place.

· One death due to hepatic failure:

- A death due to hepatic failure occurred in a male patient in the Phase 3 trial during the first cycle of melphalan/PHP treatment. Following melphalan/PHP treatment, this patient experienced fluid overload, myelosuppression, and hepatorenal syndrome. An autopsy revealed that this patient's death was related to underlying disease burden as the tumor burden in his liver was greater than 90%. A protocol amendment was implemented to address this issue. If, on radiographic imaging there is greater than 50% involvement of tumor in the liver, then a laparoscopic biopsy is necessary to ensure adequate hepatic reserve. Since the institution of this amendment, there were no further deaths due to hepatic failure.

· Two deaths were attributable to complications of a reduction in the level of white blood cells, referred to as neutropenia, beyond the first cycle of treatment. This condition makes patients more susceptible to bacterial infection.

- One patient died of streptococcal sepsis and another died of neutropenic complications. It is important to note that prophylactic growth factor support, which is used to treat neutropenia, was not protocol specified and rarely used.
- While myelosuppression is always a risk with chemotherapy, Delcath has recommended following the American Society of Clinical Oncology (ASCO) guidelines for the use of growth factors to mitigate the incidence of complicated neutropenia. In patients who have been treated with the Generation Two system, both commercially in Europe and in the US under the Expanded Access Program and compassionate use, we have not seen complicated neutropenia to date.

Additional deaths attributed by FDA:

In the FDA's presentation at ODAC, FDA disagreed with this assessment of procedure related deaths and added three additional deaths, for a total of a 7% percent death rate, in the combined Phase 2 and Phase 3 programs. Two deaths related to hepatic failure and one death related to myelosuppression, were described. Upon being advised of the FDA's assessment of these deaths, the Company requested that the cases be re-reviewed by the treating principal investigators. After this review, the treating principal investigators continue to be convinced that these patients died of disease progression. The Company believes that the three additional deaths the FDA attributed to the procedure were unrelated to treatment.

Additional concerns raised by FDA

The FDA also expressed concerns about hypotension (low blood pressure) during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression. The Company believes that protocol amendments and other procedure refinements instituted during clinical trials or in commercial experience, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials planned in the Company's Clinical Development Program.

Delcath has posted both the FDA and Company ODAC briefing materials to its website at http://delcath.com/clinical-research/clinical-bibliography.

Complete Response Letter

On September 12, 2013, the FDA issued a complete response letter (CRL) regarding the Company's NDA for Melblez Kit. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments included, but were not limited to, a statement that Delcath must perform another "well-controlled randomized trial(s) to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melblez Kit outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. The Company held a meeting with FDA to clarify components of the CRL, during which it confirmed its understanding of device and procedure safety requirements contained in the CRL. Delcath is incorporating the requirements contained in the CRL into its clinical development program for HCC. The Company is also evaluating the best path forward for an indication in ocular melanoma that is metastatic to the liver. We continue to believe that such an approval would meet a high unmet need in the United States.

Clinical Development Program

The primary focus of the Company's Clinical Development Program (CDP) is to obtain clinical data for the CHEMOSAT/Melphalan HDS system in various disease states to support regulatory approvals in various jurisdictions, including the U.S. and to support clinical adoption in Europe. Currently, the Company's efforts are directed towards initiating a global Phase 2 clinical program to study the CHEMOSAT/Melphalan HDS system for the treatment of HCC.

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Cancer Treatment Landscape

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 one of the leading causes of death worldwide, accounting for approximately 8.2 million deaths and 14.1 million new cases in 2012 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 over−all 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 and Mortality

There are two types of liver cancers: primary liver cancer and metastatic liver disease. 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. Metastatic liver disease, also called liver metastasis, 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 functions 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 to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

Hepatocellular Carcinoma (HCC)

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) were expected to occur in the U.S. during 2013, and the overall five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. Globally, with 782,000 new cases in 2012, HCC was the fifth most common cancer in men and the ninth in women according to GLOBOCAN. It has been estimated that over 40 percent of all cases of HCC occur in the People's Republic of China, which has an annual incidence of 137,000 cases. GLOBOCAN estimates indicate that HCC was responsible for 746,000 deaths in 2012 (9.1% of the total cancer deaths), making it the second most common cause of death from cancer worldwide.

The prognosis for liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society's (ACS) Cancer Facts & Figures 2013 outlines the treatment options for HCC as follows: "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."

In HCC, the impact of systemic chemotherapy has been very limited, primarily due to the poor liver function of presenting patients. Modest results have been reported in Phase II trials with various agents such as doxorubicin, gemcitabine, and capecitabine. A Phase III open label study compared advanced HCC patients who received doxorubicin or FOLFOX4 (5-fluorouracil and leucovirin plus oxaliplatin), and found no statistical difference in median overall survival. For HCC patients who are not eligible surgery or TACE, the only current FDA-approved chemotherapy option is sorafenib. Sorafenib, taken orally, is a small molecule, multikinase inhibitor with activity against Raf-1, B-raf, VEGFR2 and PDGFR- proteins and signaling pathways shown to be involved in the pathogenesis of HCC. Data from two randomized Phase III clinical trials (the SHARP trial and the Asian trial) in patients with unresectable advanced HCC with Child-Pugh A score reported very modest response rates (2%), but

demonstrated statistically significant survival advantages favoring sorafenib. Phase III trials evaluating the efficacy of sorafenib alone versus a combination of sorafenib plus doxorubicin, or sorafenib plus capecitabine and oxaliplatin (SECOX) are currently ongoing.

Despite its approval and widespread use as the first line treatment for unresectable HCC, there are challenges and limitations associated with sorafenib. High rates of dermatologic side effects, such as hand-foot skin reaction (HSFR) were reported in the SHARP and Asian Phase III trials. Acute diarrhea has also been described as an early and common side-effect of sorafenib treatment. More recently, there have been reports of pancreatic atrophy associated with long-term sorafenib therapy, possibly due to its overall anti-angiogenic activity. Resistance to sorafenib despite initial responses has also been reported. This has spurned efforts to develop other chemotherapeutics, most of which target the multiple signaling pathways and molecules involved in HCC. Notable among these are small molecule agents such as brivanib (targeting VEGFR, FGFR), ARQ 197 or tivantinib (targeting c-MET), XL184 or cabozantinib (targeting c-MET and VEGFR), and ABT-869 or linifanib (targeting VEGFR, PDGFR, c-KIT, FLT-3), and monoclonal antibody/biologics such as ramucirumab (anti-VEGFR2), all of which are currently in Phase III trials. Other agents currently in HCC or metastatic liver cancer Phase II trials include axitinib, cediranib, and oranitinib (all targeting VEGFR), lapatinib , and gefitinib (both targeting EGFR), selumetinib (targeting MEK), and belinostat (targeting histone deacetylase). In addition to these agents, MDX-1106 (also known as BMS-936558 or nivolumab), an antibody that targets the PD-1 immuno-inhibitory receptor, is in a Phase I trial for advanced HCC.

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Phase 2 Multi-Histology Clinical Trial - HCC Cohort

In the Company's multi-arm Phase 2 clinical trial, conducted between 2005 and 2010, five patients with HCC were treated with the CHEMOSAT/Melphalan HDS system in the primary hepatic malignancy cohort. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hepatic progression free survival (hPFS) ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and OS in this limited number of patients exceeded that generally associated with this patient population, and we believe constitutes a promising signal that warrants further clinical investigation.

Phase 2 HCC Program

On the basis of these encouraging results, the Company intends to initiate a new global clinical trial program in the U.S., Europe, and Asia. The Company intends to pursue a staged clinical strategy initiating a Phase 2 clinical trial program followed by a Phase 3 trial if the initial responses are positive. The Company recently filed its amended Investigational New Drug (IND) application with the FDA to include the trial protocol for its Phase 2 HCC program and intends to begin enrolling patients in the first half of 2014 pending FDA comments and institutional review board approval. We will continue to evaluate potential partnership for China as our clinical development program in HCC progresses.

EU Clinical Data Generation

In Europe, the Company has completed a retrospective data collection trial and which collected data post hoc from two hospitals in Europe where therapy with the CHEMOSAT system was administered in a non-clinical trial setting. It provided a retrospective view of hematology results from 7 patients treated with the CHEMOSAT system in Europe. The data, while not part of a formal clinical trial design and limited in nature does provide supporting evidence that the safety of Generation 2 CHEMOSAT system and related treatment appeared well tolerated and manageable. In addition, the Company is initiating a Patient Registry, which will prospectively collect data from EU commercial experience. The first hospital submitted the protocol to its Ethics Committee in January 2014 and we anticipate the first site to be enrolling patients by the end of the second quarter of 2014. We believe the Patient Registry will provide valuable data and information from a commercial setting which can be used to support our efforts for clinical adoption and commercialization in Europe. The Company also expects to help support investigator initiated trials (IITs) globally across multiple tumor types as suitable opportunities present in Europe. At present two IITs in HCC and CRC are near activation in Europe. The Company believes IITs will serve to build clinical experience at key cancer centers, and will support efforts to obtain compelling reimbursement in Europe.

Ocular Melanoma

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, current evidence suggests median overall survival for these patients is generally four to six months. According to the ACS, the incidence of ocular melanoma in 2013 was approximately 2,800 cases, with an estimated 320 deaths. Currently there is no standard of care for patients with ocular melanoma liver metastases. The Company is currently evaluating the best path forward for a potential indication for the Melphalan/HDS system in the treatment of ocular melanoma liver metastases.

Expanded Access Program

With the conclusion of the FDA's review of the Company's NDA, the Company formally closed its expanded access program for patients with unresectable liver metastases from ocular melanoma. The Company will continue to support the treatment of any patient currently enrolled under the program. Patients in the United States are able to seek treatment with Melphalan HDS system from centers offering it on a compassionate use basis.

Sales and Marketing

European Union

In April 2011 the Company obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system. The Company began European commercialization with this version of the CHEMOSAT system in early 2012 when the first CHEMOSAT procedures performed outside of a clinical trial setting were performed in Italy. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system

In the European Economic Area (EEA), the CHEMOSAT system is regulated as a Class IIb 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. As a Class IIb medical device, 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. The right to affix the CE Mark allows the Company to market and sell the CHEMOSAT system in Europe.

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With continued economic challenges in certain European markets, the Company's immediate market access and clinical adoptions efforts are focused on the key target markets of Germany and the United Kingdom, which represent a majority of the total potential liver cancer market (primary and metastatic) in the EU and where progress in securing reimbursement for CHEMOSAT treatments offers the best near-term opportunities. The Company also continues to support clinical adoption of CHEMOSAT system in the Netherlands, Italy, Spain and France. The Company uses a combination of direct and indirect sales channels to market and distribute the CHEMOSAT system in Europe. In 2013, the Company utilized medical science liaisons through a contract organization to support our clinical adoption efforts. As a part of the Company's restructuring, the medical science liaison consultant program will be phased out throughout 2014 as we integrate these capabilities into existing resources.

To support our commercialization efforts in the EU, we have established our European Headquarters in Galway, Ireland.

Since launching the CHEMOSAT system, treatments have been performed at 17 leading European cancer centers.

Germany
o University of Heidelberg Hospital
o Berlin Charité Hospital
o University Medical Center Göttingen
o Johann Wolfgang Goethe-University, Frankfurt
o University of Bonn
o Asklepios Clinic Barmbek, Hamburg
o Jena University Hospital, Jena

United Kingdom
o Southampton University Hospital
o SPIRE Southampton Hospital

Italy
o European Institute of Oncology
o Varese University Hospital

The Netherlands
o Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital
o Leiden University Medical Center

France
o Cancer Institute Gustave Roussy
o Hôpital Saint-André

Spain
o Clinica Rotger Majorca Hospital

Ireland
o University Hospital Galway

As of March 7. 2014, these centers have performed 89 procedures on 61 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.

Under the regulatory scheme in the EEA, the CHEMOSAT system has received authorization to affix the CE Mark as a device only, and physicians must separately obtain melphalan for use with the CHEMOSAT system. Our ability to market and promote the CHEMOSAT system is limited to this approved indication. Melphalan is currently approved in 14 member states of the EEA, including the seven markets where procedures have been performed.

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 system must obtain and use melphalan independently at their discretion.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. In 2013 the Company engaged a third party reimbursement specialist to support 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, the Company is actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. 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.

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Germany

In 2013, physicians and patients in Germany submitted Individual Funding Requests (IFRs) seeking reimbursement for the treatment of liver metastases with the CHEMOSAT system. IFRs are case-by-case appeals for reimbursement made to the patient's insurance carrier. While each IFR is evaluated independently, we have been advised that the majority of these applications have been approved in recent months. We expect that IFRs will be the key reimbursement vehicle in the German market in 2014.

In January 2014, the Company announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, again granted Value 4 coverage status for the treatment of patients with liver metastases with the CHEMOSAT system. Under the Neue Untersuchungs und Behandlungsmethoden (NUB) reimbursement scheme, Value 4 Status, while not mandating reimbursement, allows participating cancer centers to negotiate a budget to fund reimbursement coverage for the CHEMOSAT procedure with insurers serving their region.

The InEk determines three status levels for medical procedures submitted for its review: Value 1 (mandated reimbursement), Value 2 (declined for reimbursement), and Value 4 (negotiated reimbursement). The InEk may also decline to make determination regarding an application. For 2014 reimbursement, a total of 618 medical procedures were submitted to the InEk for consideration under the NUB scheme, with 16% or 96 procedures receiving Value 1 Status, 6% or 36 procedures receiving Value 4, and the remaining 78% denied coverage or un-evaluated. The application for CHEMOSAT was submitted by 71 hospitals in Germany, which represents a significant increase in the level of institutional support the procedure received over 2013.

InEk first established NUB Value 4 status for CHEMOSAT procedures in 2013, though we have been advised that hospitals did not successfully negotiate reimbursement budgets for CHEMOSAT in 2013. In 2014, we believe that a number of hospitals performing the CHEMOSAT procedure in Germany intend to pursue reimbursement under Value 4 status. The NUB is an annual process, and participating centers in Germany are required to apply each year for subsequent coverage under the NUB scheme.

Additionally, the German Radiology Society resubmitted its application for ZE (Zusatzentgeld) in March 2013, which is a permanent reimbursement code until a CHEMOSAT specific DRG code can be created. A ZE code is dependent on having enough financial data to establish cost averages. The application was rejected in December 2013 for insufficient cost data. The German Radiology Society is expected to resubmit an application for a ZE code with more extensive cost data at the end of March 2014, with a decision expected by the end of 2014. With seven centers now active in Germany more data can now be made available to InEk. There will be a particular focus in 2014 on ensuring that treatments and cost data are increased at those specific hospitals providing the cost calculations to InEk.

United Kingdom

In April 2013, interim funding for oncological procedures in the United Kingdom moved away from local Primary Care Trusts (PCTs) to a centralized body of cancer care commissioners. Delcath and its partner centers have identified existing Healthcare Resource Groups (HRG) code(s), which may allow hospitals to be covered for CHEMOSAT procedure related costs. The Company is also working with the HRG organization that decides on new HRG codes with a view to gaining a dedicated and permanent reimbursement code in the future.

The Company is also supporting efforts seeking a block fund grant through the Commissioning Through Evaluation (CTE) process which may provide up to 50-75 ocular melanoma patients to be treated utilizing the CHEMOSAT system in three centers across the U.K. It is important to note that the CTE process has been driven by partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. The British healthcare system continues to evolve however, and ongoing changes to the CTE process and funding streams have resulted in delays and made the granting and timing of block funding difficult to predict. The current expectation is for the process to be completed by the end of the third quarter of 2014 with the funding, if any, becoming available in the fourth quarter of 2014. The entire CTE funding mechanism is a new process and these

ongoing policy changes in the National Health Service (NHS) make it difficult to predict the likelihood of success in the near term.

In December 2013, the National Institute for Clinical Excellence (NICE), a non-departmental public body that provides guidance and advice to improve health and social care in the UK, initiated a clinical review of the CHEMOSAT procedure. NICE issued provisional draft recommendations for the use of CHEMOSAT in the UK, and invited the Company as well as physicians and other interested parties to comment. The NICE recommendations were open for public comment until January 22, 2014, and a decision on final clinical recommendations is expected April 23, 2014. NICE may decide to conduct a Technology Appraisal of the CHEMOSAT procedure thereafter, the outcome of which could influence the long-term reimbursement status.

Italy

In Italy, DRG codes identified by the Company have been inadequate to fully cover the costs of the procedure. In order to move forward, supplemental new technology payments would be required to fully fund the procedure. This process has taken longer than anticipated due to the unstable political and economic environment in the country that has delayed decisions for extra payments for new technologies. This applies not only to the CHEMOSAT procedure but to new technologies at the present time. For these reasons, commercialization in Italy has stagnated and further progress will be challenging.

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The Netherlands

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 system requires that Delcath publishes its Phase 3 data. Following publication, the application for reimbursement will be submitted. In the meantime, the Company is in close contact with the Dutch committee which sanctions new oncological treatments (BOM).

Permanent reimbursement coverage in remaining EU markets will require additional time to secure. In the interim period, the Company is seeking payment through various avenues, including new technology programs. In France, the Company has revised its strategy and decided not to pursue a multi-center STIC application. STIC is a hybrid of interim funding and clinical study, allowing a new procedure to be assessed over a two-year period on a pre-set number of treatments. The Company believes that the STIC process would be too time consuming and costly, and that direct pursuit of a DRG code represented a better allocation of Company resources in this market. The Company will also present its Phase 3 trial data, once published, to the French healthcare authorities in order to assess the possibility of gaining a DRG code without going through the STIC process. In Ireland, the Company is postponing commercialization efforts until a clear reimbursement pathway is identified.

For France and the Netherlands, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Company continues to work with the principal investigators on submission of its Phase 3 and Phase 2 clinical trials for publication. The timing of these submissions will be determined by the principal investigators and the Company looks forward to the submission of the publications.

Distribution Partners

As a result of the Company’s strategy to prioritize resources on the key direct markets of Germany and the United Kingdom, the Company expects that its distribution strategy in indirect markets like Italy and Spain will play a lesser role in its current commercial activities. Similarly, while Delcath had secured distribution partners in Hong Kong, Taiwan and Argentina, we have deferred commercialization efforts in these markets at this time in order to focus on the priority commercial markets.

Other International Markets

The Company will continue to evaluate opportunities in other markets on a case by case basis.

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 continued economic weakness, which is affecting healthcare budgets and reimbursement.

The CHEMOSAT/Melphalan HDS system competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In 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 HCC, sorafenib (Nexavar, Onyx Pharmaceuticals) remains the only targeted drug approved for the treatment of HCC in patients who are not candidates for surgery.

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 Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar™, GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST™, GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease.

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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 alternative treatment methods, or achieve earlier product development, in which case the likelihood of us 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 the EEA, the CHEMOSAT system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the European Union plus 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 system is 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 system 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 is regulated as a Class IIb medical device. As a Class IIb medical device, 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.

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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 system 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

The CHEMOSAT device has received registrations in the following countries: Australia, New Zealand, Argentina, Taiwan, and Singapore. With limited resources and our attention focused on European commercial and clinical adoption efforts, pursuing other markets at this time is not practical. The Company will continue to evaluate commercial opportunities in these and other markets when resources are available and at an appropriate time. .

United States Regulation

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), and it's implementing regulations. The Delcath Melphalan/HDS system 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 Melphalan/HDS System, 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;

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- 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 a New Drug Application (NDA). NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which 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. For new oncology products, the FDA will often solicit an opinion from an Oncologic Drugs Advisory Committee (ODAC), 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 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 (CRL) if the applicable regulatory criteria are not satisfied. A CRL 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.

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There are three primary regulatory pathways for a New Drug Application under Section 505 of The Federal Food Drug and Cosmetics Act (FFDCA): Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) who active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FFDCA 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. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

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. The Company's NDA was accepted for filing by the FDA on October 15, 2012, and was designated for standard review with an initial PDUFA goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013. The FDA's Oncologic Drugs Advisory Committee (ODAC) reviewed its NDA on May 2, 2013, and voted 16 to 0, with no abstentions, that the benefits of treatment with the Melblez Kit do not outweigh the risks associated with the procedure using the early clinical trial versions of the system. On September 12, 2013, the FDA issued a complete response letter (CRL) regarding the Company's NDA for Melblez Kit

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 five 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. In October 2013, the FDA granted Delcath orphan drug designation of the drug melphalan for the treatment of HCC.

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. 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 any potential approvals of an NDA for that product.

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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.

Manufacturing and Quality Assurance

We manufacture certain components including our proprietary filter media, and assemble and package the CHEMOSAT/Melphalan HDS 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/Melphalan HDS system. The CHEMOSAT/Melphalan HDS 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.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how 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, twelve foreign patents with patent validity in 28 countries, seven pending United States patent applications, and eight pending foreign patent applications.

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/Melphalan HDS 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.

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Certain of our United States and foreign patents have already expired and other patents relating to the CHEMOSAT/Melphalan HDS system will expire in 2016. 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 if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted Delcath five 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 once commercialization of an orphan drug designated product begins.

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

During 2013 the Company implemented reductions in workforce and strategic reorganizations designed to increase efficiencies and focus available financial resources on its clinical development program and European commercialization. The Company believes that these actions will help preserve the Company's ability to initiate its strategic objectives in 2014. As of December 31, 2013, the Company had 37 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Leadership Transition

On September 13, 2013, the Company announced that its Board of Directors had implemented a leadership transition plan under which Jennifer Simpson, Ph.D., M.S.N., C.R.N.P., the Company's Executive Vice President, Global Head of Business Operations, and Graham Miao, Ph.D., M.S., MBA, the Company's Executive Vice President and Chief Financial Officer, were appointed to serve as Interim Co-President and Co-Chief Executive Officers. The employment of Eamonn P. Hobbs as President and Chief Executive Officer with the Company was terminated on September 10, 2013 and Mr. Hobbs also resigned from the Board of Directors.

In addition to her role as Interim Co-President and Co-Chief Executive Officer, Dr. Simpson continues to serve as the Company's Executive Vice President, Global Head of Business Operations. In addition to his role as Interim Co-President and Co-Chief Executive Officer, Dr. Miao continues to serve as the Company's Executive Vice President, Chief Financial Officer.

Under the leadership transition, Gabriel Leung was appointed Chairman of the Board. Mr. Leung has been a member of the Board of Directors since 2011. He replaces Dr. Harold Koplewicz as Chairman, who remains a member of the Board of Directors.

Transition Committee

The Board has also appointed a Transition Committee to assist the Board and management with the leadership transition. This Committee will also assist the Board in evaluation of potential strategic options for the Company going forward. The current members of this Committee are Board members Mr. Douglas Watson, Mr. Roger Stoll, Dr. Harold Koplewicz and Mr. Gabriel Leung.

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.

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Item 1A. Risk Factors

Risks Related to Our Business and Financial Condition

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We received a complete response letter from the FDA regarding our Melblez Kit system, which precludes approval of our existing NDA.
Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

In September 2013, the FDA issued a complete response letter (CRL) with respect to our NDA seeking an indication or ocular melanoma liver metastases for our Melblez Kit system. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments in the CRL included, but were not limited to, a statement that Delcath must perform additional “well-controlled randomized trial(s) to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure” and which “demonstrates that the clinical benefits of Melblez Kit outweigh its risks.” The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market.

As a part of the regulatory process of obtaining marketing clearance for the Melphalan/HDS system, we will conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. We presently have plans to conduct a Phase II clinical trial program for HCC. Unfavorable or inconsistent clinical data from clinical trials, including the Phase II clinical trial program for HCC 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. Additionally, even if the results of our Phase II clinical trial program for HCC are positive, there is a substantial risk that it will fail to have positive results in Phase III clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

We do not expect to generate significant revenue for the foreseeable future.
Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of the CHEMOSAT/Melphalan HDS system and currently we have only developed this system for the treatment of cancers in the liver. If the CHEMOSAT/Melphalan HDS 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 CHEMOSAT system is currently only authorized for marketing in the EEA, Australia, New Zealand and Taiwan, if we are unsuccessful in commercializing the product in the EEA and if the Melphalan HDS system is not approved in the United States and elsewhere, we will have no means of generating revenue. In September 2013, the FDA issued a CRL with respect to our NDA for our Melblez Kit system. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its then current form. Accordingly, we do not expect to realize any revenues from product sales in the United States in the next several years, if at all. As a result, our revenue sources are, and will remain, extremely limited until our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. The CHEMOSAT/Melphalan HDS system may not be successful in clinical trials, approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Continuing losses may exhaust our capital resources.
As of December 31, 2013, we had $31.2 million in cash and cash equivalents. We have had minimal revenue to date, and we have a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended

December 31, 2013, 2012, and 2011, we incurred net losses of approximately $30.7 million, $51.9 million and $30.9 million, respectively, and we expect to continue to incur losses in 2014. 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/Melphalan HDS system or any other versions of the system.

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/Melphalan HDS system, complete our Phase II HCC clinical trial program 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 complete our Phase II HCC clinical trial program 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 commercialize the CHEMOSAT/Melphalan HDS system commercially, obtain regulatory approvals or complete our development projects or our clinical trials.

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

- clinical studies, including a Phase II clinical trial program to establish proof of concept in HCC;
- 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.

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/Melphalan HDS 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 Melphalan HDS 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 Melphalan HDS 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 Melphalan HDS 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;
- o

- 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 Melblez Kit system NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA issued a CRL. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments in the CRL included, but were not limited to, a statement that Delcath must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melblez Kit outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

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- adversely affect the commercialization of the current CHEMOSAT/Melphalan HDS 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 CHEMOSAT system, our ability to commercialize the CHEMOSAT 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 hydrochloride, 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 are 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 CHEMOSAT system, our ability to commercialize the CHEMOSAT 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 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 CHEMOSAT 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 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/ Melphalan HDS 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/Melphalan HDS system may include implementation of a risk evaluation and mitigation strategies (REMS) program 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;

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- 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 Melphalan HDS system by the FDA for use in the United States.

We cannot sell or market the Melphalan HDS system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Melphalan HDS 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 Melphalan HDS 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 Melphalan HDS 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 Melphalan HDS 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.

In August 2012, we submitted a NDA seeking an indication or ocular melanoma liver metastases for our Melblez Kit system . In September 2013, the FDA issued a complete response letter (CRL). A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments in the CRL included a statement that Delcath must perform additional well-controlled randomized trials to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melblez Kit outweigh its risks. Failure to obtain FDA approval would have a material adverse effect on our business, financial condition and results of operations.

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. If the FDA approves an application for the Melblez Kit, our ability to market and promote the Melblez Kit system would be limited to the approved indication, 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 future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the Melphalan HDS 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 Melphalan HDS system in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase II clinical trial of the Melphalan HDS system 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.

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We intend to conduct a Phase II clinical trial program to establish proof of conceptin HCC, as well as other clinical trials for other indications, and it may take several years to complete the testing of the Melphalan HDS system for use in the treatment of this indication, 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 Melphalan HDS system for other indications. If we are unable to develop the Melphalan HDS 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 Melphalan HDS system in certain types of cancer. Such limited data could slow the adoption of our CHEMOSAT/ Melphalan HDS system, significantly reduce our ability to commercialize the CHEMOSAT/ Melphalan HDS system.

We rely on third parties to conduct certain of the clinical trials for the CHEMOSAT/ Melphalan HDS 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 Melphalan HDS 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. We intend to rely upon third parties to conduct monitoring and data collection of our future clinical trials, including our planned Phase II HCC clinical trial program. 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 or other foreign regulatory agencies 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 Melphalan HDS system if these requirements are not met.

Purchasers of the 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 CHEMOSAT system in the EEA.

We have obtained the right to affix the CE Mark for the 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 CHEMOSAT system. 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.

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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 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.

The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.

Our ability to commercialize our systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The CHEMOSAT/Melphalan HDS system is currently not approved by the FDA or any other regulatory body outside the EEA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the Melphalan HDS system's use since the product is currently not approved outside the EEA. We will seek reimbursement by third-party payors of the cost of the Melphalan HDS system after its use is approved, but there are no assurances that adequate third-party coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize the CHEMOSAT/ Melphalan HDS system and the demand for the CHEMOSAT/ Melphalan HDS 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/Melphalan HDS system.

Our CHEMOSAT/ Melphalan HDS system may not achieve sufficient acceptance by the medical community to sustain our business.

The commercial success of the CHEMOSAT/Melphalan HDS system will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. If testing and clinical practice do not confirm the safety and efficacy of the CHEMOSAT/Melphalan HDS system or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, the CHEMOSAT/Melphalan HDS system as effective and desirable, our efforts to market the CHEMOSAT/Melphalan HDS system may fail, which would have an adverse effect on our business, financial condition and results of operations.

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 and foreign markets may 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/Melphalan HDS 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/Melphalan HDS 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/Melphalan HDS system, thereby harming our results of operations.

We may not realize the expected benefits from our restructuring and optimization initiatives; our long-term expense reduction programs may result in an increase in short-term expense; and our efforts may lead to additional unintended consequences.

In early 2013, we announced a plan to increase efficiencies and reduce cash utilization. To achieve the program's goals, we broadened our workforce restructuring actions throughout 2013. As a result of the restructuring program and attrition, we reduced our workforce by approximately 60% in 2013. In addition, we sought to reduce expenses incurred with outside consultants and announced that we were pursuing a relocation project to move our New York City operations to a more cost effective satellite office in New Jersey. These measures could have unintended consequences, such as distraction of our management and employees, business disruption, attrition beyond our planned reduction in workforce and reduced employee productivity. We may be unable to attract or retain key personnel. Attrition beyond our planned reduction in workforce or a material decrease in employee morale or productivity could negatively affect our business and results of operations. In addition, headcount reductions may subject us to the risk of litigation, which could result in substantial cost. These measures, or other expense reduction measures we take in the future, may not result in the expected cost savings.

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If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

We may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our programs and even cease development and commercialization of the CHEMOSAT/Melphalan HDS system;
- suffer the loss of key personnel, or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the CHEMOSAT/Melphalan HDS 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 CHEMOSAT system is approved for marketing as a device only, and doctors will separately obtain melphalan for use with the 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 may seek to market the 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/ Melphalan HDS system from third parties, some of which are sole-source suppliers.

The components of the CHEMOSAT/Melphalan HDS 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/Melphalan HDS 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/Melphalan HDS 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/Melphalan HDS system to the market.

All of the manufacturers of the components for the CHEMOSAT/Melphalan HDS 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/Melphalan HDS system could be jeopardized. The CHEMOSAT/Melphalan HDS 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.

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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 or complete our planned Phase II clinical trial program for HCC.

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 use the melphalan supplied by Synerx and Bioniche to conduct our planned Phase II clinical trial program for HCC. We may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for our clinical trial program and the commercialization of the CHEMOSAT/Melphalan HDS 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/Melphalan HDS system, our ability to develop and commercialize the system would be impaired.

We manufacture the CHEMOSAT/Melphalan HDS 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 sufficient 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/Melphalan HDS system to purchasers.

In addition to limiting sales opportunities, delays in manufacturing the CHEMOSAT/Melphalan HDS 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/Melphalan HDS 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/Melphalan HDS 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/Melphalan HDS system.

We do not have written contracts with all our suppliers for the manufacture of components for the CHEMOSAT/Melphalan HDS 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/Melphalan HDS system in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of the CHEMOSAT/Melphalan HDS system are currently manufactured for us in small quantities and we may require significantly greater quantities to further 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/Melphalan HDS 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 CHEMOSAT system in the EEA.

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 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 CHEMOSAT system, our ability to generate revenues in the EEA may be harmed, and we may not generate sufficient revenue to sustain our business or 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

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Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing the CHEMOSAT/Melphalan HDS 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/Melphalan HDS system may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. If we are unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market our products in the United States or foreign countries, particularly in Asia, our efforts to commercialize the CHEMOSAT/Melphalan HDS system or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing the CHEMOSAT/Melphalan HDS 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 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/Melphalan HDS system may not be successful.

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/Melphalan HDS 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/Melphalan HDS 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 CHEMOSAT system in the EEA, 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;
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- 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.

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The 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 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 CHEMOSAT 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/Melphalan HDS 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/Melphalan HDS system for other indications could affect our orphan drug exclusivity. 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. In October 2013, the FDA granted Delcath orphan drug designation of the drug melphalan for the treatment of HCC. If the CHEMOSAT/Melphalan HDS 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 harm our business. 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.

We have been named as a party to a purported stockholder class action and stockholder derivative complaint, and we may be named in additional litigation, all of which will require significant management time and attention, result in substantial legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on us.

A purported class action lawsuit has been filed against us on behalf of certain purchasers of our common stock. The complaint includes allegations that we violated federal securities laws by, among other things, knowingly making false and misleading statements or omissions regarding our NDA for our Melblez Kit, thereby artificially inflating the price of our common stock. The complaint seeks compensatory damages, equitable relief, and reasonable attorneys' fees, expert fees and other costs. In addition, stockholder derivative actions have been initiated against us and certain of our directors and officers. These complaints purport to seek relief on behalf of the company to remedy alleged breaches of fiduciary duty and other misconduct by the defendants. Our insurance coverage and assets may be insufficient to cover any damage awards or settlement arrangements we may enter into in connection with such claims. Any such payments or settlement arrangements in this current litigation or any future litigation could have material adverse effects on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, this or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, such lawsuits may make it more difficult for us to finance our operations.

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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/Melphalan HDS 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/Melphalan HDS system have expired in 2013 and will continue to expire 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/Melphalan HDS 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.

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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.

We rely solely on trade secret protection for important proprietary technologies in the EEA.

We presently only have a validly issued patent with claims related to certain features of the current version of the CHEMOSAT/Melphalan HDS system in the United States and other parts of the CHEMOSAT/Melphalan HDS system are protected by trade secret. Outside the United States, we have no patent protection for the CHEMOSAT/Melphalan HDS system and rely on trade secret protection. Without patent protection in the EEA, the 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/Melphalan HDS system will significantly impair our ability to commercialize the 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/Melphalan HDS system in these countries, our ability to successfully commercialize the CHEMOSAT/Melphalan HDS 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 clinical trials and the testing, manufacture, marketing, sale and use of the CHEMOSAT/Melphalan HDS system. In addition, because the CHEMOSAT/Melphalan HDS 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

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- fluctuations in our quarterly operating results or the operating results of our competitors;
- variance in our financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving our company, our general industry or both;
- recruitment or departure of key personnel;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by our stockholders; and
- the trading volume of our common stock.

In addition, the stock markets, in general, the NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

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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 $0.16 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 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.

Our common stock is listed on The NASDAQ Capital Market and if we do not maintain compliance with NASDAQ Marketplace Rules our common stock may be delisted from the NASDAQ Capital Market.
To keep our listing on The NASDAQ Capital Market, 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. On June 13, 2013, we were notified by the NASDAQ Listing Qualifications Department that we do not comply with the $1.00 minimum bid threshold as our common stock has traded below the $1.00 minimum bid price for 30 consecutive business days. We were automatically provided with a 180-calendar day period within which to regain compliance and we have qualified for an additional 180-day grace period, which ends on June 9, 2014. To regain compliance, our common stock must close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. On February 24, 2014, we obtained shareholder approval of an amendment to our Certificate of Incorporation to effect a reverse stock split of our common stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014. Our board of directors was also granted the authority to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing and ratio. Our board of directors has not determined when, if ever, we will effect a reverse stock split and even if we do effect a reverse stock split our common stock still may not trade above the $1.00 minimum bid price.

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, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our

common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

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.

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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, 2013, we had an aggregate of 16.8 million shares of common stock authorized but unissued and the number of authorized but unissued shares will be significantly increased if we effect the reverse stock split approved by our stockholders on February 24, 2014. 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 business combinations or acquisitions of other companies and assets, and we may issue shares of common stock in connection with those transactions. 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 United States 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 containing approximately 10,320 square feet 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 approximately six acres of 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, but can be terminated after the fifth year (August 2016). 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.

In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York (Case No. 13-cv-3116)

On May 8, 2013, a purported stockholder of the Company filed a putative class action complaint in the United States District Court for the Southern District of New York, captioned Bryan Green, individually and on behalf of all others similar situated, v. Delcath Systems, Inc., et al. ("Green"), Case No. 1:13-cv-03116-LGS. On June 14, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Joseph Connico, individually and on behalf of all others similarly situated, v. Delcath Systems, Inc., et al. ("Connico"), Case No. 1:13-cv-04131-LGS.

At a hearing on August 2, 2013, the Court consolidated the Green and Connico actions under the caption In re Delcath Systems, Inc. Securities Litigation, No. 13-cv-3116, appointed Lead Plaintiff, Delcath Investor Group, and approved Pomerantz Grossman Hufford Dahlstrom & Gross LLP as Lead Plaintiff's choice of counsel.

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On September 18, 2013, Lead Plaintiff filed a consolidated amended complaint, naming the Company and Eamonn P. Hobbs as defendants (the "Defendants"). The consolidated amended complaint asserts that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by allegedly making false and misleading statements or omissions regarding the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma in the liver. The putative class period alleged in the amended complaint is April 21, 2010 through and including September 13, 2013. Lead Plaintiff seeks compensatory damages, equitable relief, and reasonable attorneys' fees, expert fees and other costs. On October 31, 2013, Defendants filed their motion to dismiss, which is fully briefed and currently pending.

The Company believes that the In re Delcath Systems, Inc. Securities Litigation action lacks merit and intends to defend the case vigorously.

In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS)

On May 23, 2013, purported stockholders of the Company filed a shareholder derivative lawsuit in the United States District Court for the Southern District of New York, captioned Vincent J. Orlando and Carol Orlando, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Orlando"), Case No. 1:13-cv-03494-LGS. On June 11, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Howard Warsett, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Warsett"), Case No. 1:13-cv-04002-LGS. On July 19, 2013, another substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Patricia Griesi, derivative on behalf of nominal defendant Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Griesi"), Case No. 13 cv 5024. In all three cases, Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung were named as defendants (the"Individual Defendants"), and the Company was named as a nominal defendant.

All three complaints assert claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, and gross mismanagement for making false and misleading statements or failing to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. In addition, the Orlando complaint further asserts claims for contribution and indemnification, abuse of control, and waste of corporate assets, while the Warsett complaint asserts an additional claim for unjust enrichment. The Griesi complaint also asserts additional claims for breach of fiduciary duties for failing to maintain internal controls, unjust enrichment, abuse of control, and violations of Section 14(a) of the Securities Exchange Act of 1934. The relevant time period alleged in the Orlando action is April 21, 2010 through the present, and the relevant time period alleged in the Warsett action is April 10, 2010 through the present. The relevant time period alleged in Griesi is April 21, 2010 through May 2, 2013. The Orlando, Warsett and Griesi plaintiffs seek damages as well as reasonable costs and attorneys' fees. The Griesi plaintiffs also seek corporate governance reforms and improvements and restitution.

On June 25, 2013, the Court consolidated the Orlando and Warsett actions with the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS ("Consolidated Derivative Case"). On August 1, 2013, the Court consolidated the Griesi action under the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS. At a hearing on August 2, 2013, the Court entered an order approving Federman & Sherwood as lead counsel. The Court stayed the Consolidated Derivative Case, pending resolution of an anticipated motion to dismiss in In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York, No. 13-cv-3116.

The defendants in the Consolidated Derivative Case deny any wrongdoing, believe the claims are baseless, and will defend the case accordingly.

Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., Supreme Court of the State of New York County of New York (Case No. 652030/2013)

On June 7, 2013, a purported stockholder of the Company filed a shareholder derivative lawsuit in the Supreme Court of the State of New York County of New York, captioned Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., ("Weinstein") Case No. 652030/2013. The action named Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung as individual defendants (the "Individual Defendants"), as well as the Company, as a nominal defendant.

The complaint asserts claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets in connection with allegations that the Individual Defendants made false and misleading statements or failed to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. The relevant time period alleged is April 21, 2010 through the present. The plaintiff seeks damages, as well as reasonable costs and attorneys' fees.

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On July 16, 2013, the parties in the Weinstein matter stipulated to stay the proceeding until the federal district court rules on the anticipated motion to dismiss in In re Delcath Systems, Inc. Securities Litigation, No. 13-cv-3116.

The defendants in the Weinstein matter deny any wrongdoing, believe the claims are baseless, and will the case defend accordingly.

Item 4. Removed and Reserved.

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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

	2013	
	High	Low
Quarter ended March 31, 2013	$2.13	$1.30
Quarter ended June 30, 2013	1.91	0.37
Quarter ended September 30, 2013	0.43	0.30
Quarter ended December 31, 2013	0.59	0.23

	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

On March 11, 2014 there were 88 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, 2013, 2012 and 2011.

Performance Graph

The graph below matches the cumulative 5-Year total return of holders of Delcath Systems Inc.'s common stock with the cumulative total returns of the NASDAQ Composite index and a customized peer group of fifteen companies that includes: Acura Pharmaceuticals Inc, Adamis Pharmaceuticals Corp., Alkermes PLC, Aradigm Corp., Columbia Laboratories Inc., Delcath Systems Inc., Flamel Technologies SA, Generex Biotechnology Corp., Hospira Inc, Insite Vision Inc., Intellipharmaceutics International Inc., Novadel Pharma Inc., Petmed Express Inc., Psivida Corp. and Valeant Pharmaceuticals International Inc. The graph assumes that the value of the investment in our common stock, in each index, and in the peer group (including reinvestment of dividends) was $100 on 12/31/2008 and tracks it through 12/31/2013.

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	12/08	12/09	12/10	12/11	12/12	12/13
Delcath Systems Inc.	100.00	429.41	823.53	256.30	103.36	21.43
NASDAQ Composite	100.00	144.88	170.58	171.30	199.99	283.39
Industry Group 513 - Drug Delivery	100.00	161.20	207.51	218.59	256.66	472.13

	12/08	12/09	12/10	12/11	12/12	12/13
Delcath Systems Inc.		329.41%	91.78%	-68.88%	-59.67%	-79.27%
NASDAQ Composite		44.88 %	17.74%	0.42 %	16.75 %	41.70 %
Industry Group 513 - Drug Delivery		61.20 %	28.73%	5.34 %	17.42 %	83.95 %

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

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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, 2013, 2012, 2011, 2010, and 2009 and for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 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)	2013	2012	2011	2010	2009
Statement of Operations Data					
Total revenue	$790	$346	$-	$-	$-
Costs and expenses	33,345	54,178	46,456	30,743	13,536
Operating loss	33,019	53,871	46,456	30,743	13,536
Net loss	30,324	51,868	30,885	46,684	22,057
Basic loss per share	(0.30)	(0.85)	(0.68)	(1.20)	(0.82)

	Year Ended December 31,				
(Dollars in thousands)	2013	2012	2011	2010	2009
Balance Sheet Data					
Current assets	$34,028	$26,432	$31,988	$48,898	$36,286
Total assets	37,097	30,474	35,241	50,578	36,807
Current liabilities	6,632	10,156	8,837	21,197	13,049
Stockholder's equity	30,099	20,009	26,104	29,081	23,758

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

Overview

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan HDS)—is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's initial focus is on the treatment of primary and metastatic 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 for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe.

In the United States, the Melphalan HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States.

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, the progress and results of clinical trials, 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, 2013, the Company had cash and cash equivalents totaling $31.2 million, as compared to cash and cash equivalents totaling $23.7 million at December 31, 2012. During the year ended December 31, 2013, the Company used $34.1 million of cash in its operating activities, which compares to $50.0 million used for operating activities during the comparable twelve month period in 2012. The decrease of $15.9 million is primarily driven by a reduction in regulatory and clinical costs related to the NDA submission, a decrease in compensation related expenses as the Company reduced the number of employees from 92 employees at December 31, 2012 to 37 employees at December 31, 2013, and improved efficiency in organization and operations. The Company believes it has sufficient capital to fund operating activities through the first half of 2015.

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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 HCC or other 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, 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, 2012, and 2013, registered direct offerings in 2007, 2009 and 2013, and "at the market" equity offering programs initiated in 2012 and 2013. For a detailed discussion of the Company's various sales of securities and the "at the market" equity offering program see Note 10 to the Company's audited financial statements contained in this Annual Report on Form 10-K.

During the three months ended March 31, 2013, the Company sold approximately 14.2 million shares of its common stock under a sales agreement with Cowen and Company, LLC through an "at the market" equity offering program for proceeds of approximately $20.9 million, with net cash proceeds after related expenses of approximately $20.8 million. There are no shares of common stock of the Company remaining for sale under this sales agreement or registered pursuant to registration statement on Form S-3 (333-165677).

As of December 31, 2013, the Company had two active registration statements.

On March 13, 2013, the Company filed a registration statement on Form S-3 with the SEC and also entered into a new sales agreement (the "March 2013 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 $50,000,000, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. The registration statement became effective on May 1, 2013 (333-187230). As of December 31, 2013, Delcath had approximately $44.1 million available under this registration statement and intends to use this for its "at the market" equity offering program, assuming sufficient shares are available to be issued.

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 10 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. and registered direct offering in October 2013 detailed in Note 10 to the Company's audited financial statements contained in this Annual Report on Form 10-K. As of December 31, 2013, Delcath had approximately $80.5 million available under this registration statement, of which approximately $5.0 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.

The Company held a Special Meeting of Stockholders on February 24, 2014 to approve an amendment to our amended and restated certificate of incorporation to effect a reverse stock split of our Common Stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014 and to grant authorization to the Board of Directors to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing and ratio. This proposal was approved by shareholders.

The Board of Directors strongly believes that the reverse stock split is necessary for the following reasons:

- To maintain the Company’s listing on The NASDAQ Capital Market.
- To provide the Company with resources and flexibility with respect to our capital sufficient to execute our business plans and strategy.

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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, 2013 (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	$8.6	$1.5	$3.6	$3.3	$0.2

Our operating lease obligations at December 31, 2013 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, but can be terminated after the fifth year (August 2016) upon not less than six months' notice. See Part I, Item 2, "Properties" and Note 12 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 adequate resources to fund operations through the first half of 2015 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, 2013; Comparisons of Results of the Years Ended December 31, 2012 and 2011

Revenue

The Company recorded approximately $0.8 million in total revenue during the year ended December 31, 2013, of which $0.3 million is related to the recognition of previously deferred revenue as a result of satisfying certain requirements of the Company's agreement with Chi-Fu Trading Co. Ltd. The remainder of the revenue is related to product sales. During the same period in 2012, Delcath recorded $0.3 million in revenue related to product sales.

Cost of Goods Sold

During the year ended December 31, 2013, the Company recognized cost of goods sold of approximately $0.5 million related to product revenue of $0.5 million. Due to adjustments in the anticipated use of inventory, the Company recorded $0.3 million cost for expired, obsolete and slow-moving inventory during the year ended December 31, 2013.

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. 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

CHEMOSAT system in April 2012, including components used in the kits sold during those periods.

As Delcath continues its commercialization in Europe, 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 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; scrapping of inventory due to expiration, obsolescence or slow-moving product, an improvement in efficiencies as the Company increases its production of the CHEMOSAT system; and the potential use of third party distributors, whose purchase prices will be lower than direct to end user customer prices.

Operating Expenses

Selling, General and Administrative Expenses

For the year ended December 31, 2013, selling, general and administrative expenses decreased to $20.7 million from $28.0 million for the year ended December 31, 2012. The decrease reflects the Company's efforts to increase organizational efficiencies, including workforce restructurings initiated early in 2013 and efforts to streamline its European operations to focus on key direct markets. During the first half of 2012, the Company incurred certain expenses related to the early stages of its European commercial activities, including creating the appropriate subsidiaries, and the hiring of staff for sales and support positions across Europe.

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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 was related to the Company's expansion, particularly as Delcath executed on its commercialization plans by hiring staff for sales and support positions across Europe. This led to an increase in personnel-related expenses, as well as all other expenses related to maintaining an office and supporting employees in Europe.

Research and Development Expenses

For the year ended December 31, 2013, research and development expenses decreased to $12.7 million from $26.2 million for the year ended December 31, 2012. The decrease is primarily due to a significant reduction in regulatory and clinical expenses related to the Company's NDA submission to the FDA.

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 was 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.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the year ended December 31, 2013, the Company had interest income of $19,777 as compared to interest income of $19,358 for the same period in 2012.

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.

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 11 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, 2013 of $30.3 million, a decrease of $21.5 million, or 41.4%, compared to the net loss from continuing operations for the same period in 2012. This decrease is primarily due to a $20.8 million decrease in operating expenses. The decrease in operating expenses reflects a significant decrease in costs related to the Company's NDA filing and overall operations.

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 was 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 reflected 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.

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 3 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 commercial organization.

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.

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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 9 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 October 2013, the Company completed the sale of 21.0 million shares of its common stock and the issuance of warrants to purchase 9.4 million common shares (the "2013 Warrants") pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of

approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 Warrants. The fair value of the 2013 Warrants on October 28, 2013 was determined by using an option pricing model assuming a risk free interest rate of 1.31%, volatility of 89.27% and an expected life equal to the contractual life of the 2013 Warrants (October 2018). The 2013 Warrants will become exercisable at $0.44 per share on April 30, 2014. The 2013 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In May 2012, the Company completed the sale of 15.3 million shares of its common stock and the issuance of warrants to purchase 4.6 million 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 October 2013 sale of common stock and warrants. At December 31, 2013, the 2012 Warrants were exercisable at $0.16 per share with 4.4 million 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.

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In June 2009, the Company completed the sale of 0.9 million shares of its common stock and the issuance of warrants to purchase 1.0 million 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 October 2013 sale of common stock and warrants. At December 31, 2013, the 2009 Warrants were exercisable at $0.16 per share with 1.0 million shares 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.

The $1.9 million in proceeds allocated to the 2013 Warrants, 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 that are subject to mark-to-market adjustment each period. As a result, for the twelve month period ended December 31, 2013, the Company recorded pre-tax derivative instrument income of $2.8 million. The resulting derivative instrument liabilities totaled $2.3 million at December 31, 2013. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2013 was determined by using an option pricing model assuming the following:

	2013 Warrants		2012 Warrants		2009 Warrants	
Expected volatility	90.75	%	106.77	%	128.50	%
Risk-free interest rates	1.63	%	0.26	%	0.10	%
Expected life (in years)	4.83		1.41		0.45	

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Item 8. Consolidated Financial Statements

Consolidated Financial Statements:

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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, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. 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. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Delcath Systems, Inc. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP
Metro Park, NJ
March 12, 2014
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DELCATH SYSTEMS, INC.
Consolidated Balance Sheets as of December 31, 2013 and 2012
(in thousands, except share data)

	December 31, 2013	December 31, 2012
Assets:		
Current assets		
Cash and cash equivalents	$31,249	$23,726
Accounts receivables, net	349	144
Inventories	719	1,105
Prepaid expenses and other current assets	1,711	1,457
Total current assets	34,028	26,432
Property, plant and equipment, net	3,069	4,042
Total assets	$37,097	$30,474
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$582	$939
Accrued expenses	3,740	5,790
Warrant liability	2,310	3,427
Total current liabilities	6,632	10,156
Long term liabilities		
Deferred revenue	6	309
Accrued expenses	360	–
Total long term liabilities	366	309
Commitments and contingencies (Note 12)	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2013 and 2012	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 134,310,337 and 76,849,033 shares issued and 134,282,237 and 76,820,933 outstanding at December 31, 2013 and December 31, 2012, respectively	1,343	768
Additional paid-in capital	257,843	218,063
Accumulated deficit	(229,132)	(198,808)
Treasury stock, at cost; 28,100 shares at December 31, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	96	37
Total stockholders' equity	30,099	20,009
Total liabilities and stockholders' equity	$37,097	$30,474

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.
Consolidated Statements of Operations and Comprehensive Loss
for the Years Ended December 31, 2013, 2012 and 2011
(in thousands, except share and per share data)

	Year ended December 31,		
	2013	2012	2011
Product revenue	$490	$346	$—
Other revenues	300	—	—
Total revenue	790	346	—
Costs of goods sold	(464)	(39)	—
Gross profit	326	307	—
Operating expenses			
Selling, general and administrative	$20,657	$27,963	$21,283
Research and development	12,688	26,215	25,173
Total operating expenses	33,345	54,178	46,456
Operating loss	(33,019)	(53,871)	(46,456)
Change in fair value of warrant liability, net	2,756	2,159	15,566
Interest income	20	19	5
Other expense and interest expense	(81)	(175)	—
Net Loss	$(30,324)	$(51,868)	$(30,885)
Common Share data:			
Basic loss per share	$(0.30)	$(0.85)	$(0.68)
Diluted loss per share	$(0.31)	$(0.85)	$(0.68)
Weighted average number of basic common shares outstanding	100,809,824	61,275,527	45,236,921
Weighted average number of diluted common shares outstanding	105,104,177	61,275,527	45,236,921
Other comprehensive income (loss):			
Foreign currency translation adjustments	$59	$37	$—
Unrealized loss on securities	—	—	26
Other comprehensive income, total	59	37	26
Comprehensive loss	$(30,265)	$(51,831)	$(30,859)

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.
Consolidated Statements of Stockholders' Equity
for the Years Ended December 31, 2013, 2012 and 2011
(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, 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
Compensation expense for issuance of stock options	-	-	-	-	174	-	-	174
Compensation expense for issuance of restricted stock	137,651	1	-	-	116	-	-	117
Sale of common stock, net of expenses	57,120,964	572	-	-	40,888	-	-	41,460
Exercise of warrants	202,689	2	-	-	241	-	-	243
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	-	-	-	-	218	-	-	218
Fair value of warrants issued classified as liability	-	-	-	-	(1,857)	-	-	(1,857)
Net loss	-	-	-	-	-	(30,324)	-	(30,324)
Foreign currency translation	-	-	-	-	-	-	59	59
Balance at December 31, 2013	134,310,337	$ 1,343	(28,100)	$ (51)	$ 257,843	$ (229,132)	$ 96	$ 30,099

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows
for the Years Ended December 31, 2013, 2012, and 2011 (in thousands)

	Year ended December 31,		
	2013	2012	2011
Cash flows from operating activities:			
Net loss	$(30,324)	$(51,868)	$(30,885)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	174	2,807	3,605
Restricted stock compensation expense	117	1,018	654
Depreciation expense	1,126	1,331	1,035
Loss on disposal of equipment	5	—	—
Warrant liability fair value adjustment	(2,756)	(2,159)	(15,566)
Non-cash interest income	(1)	2	—
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other current assets	(235)	(228)	553
Decrease in investment in common stock	—	—	26
Decrease (increase) in accounts receivable	(211)	(144)	—
Decrease (increase) in inventories	391	(1,105)	—
Increase (decrease) in accounts payable and accrued expenses	(2,445)	331	3,206
Increase in deferred revenue and long-term accrued expenses	57	9	—
Net cash used in operating activities	(34,102)	(50,006)	(37,372)
Cash flows from investing activities:			
Purchase of property, plant, and equipment	(142)	(2,120)	(2,607)
Purchase of short-term investments and marketable equity securities	—	—	(4,980)
Proceeds from maturities of short-term investments	—	4,980	1,492
Net cash (used in) provided by investing activities	(142)	2,860	(6,095)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	41,702	45,058	23,623
Net cash provided by financing activities	41,702	45,058	23,623
Foreign currency effects on cash	65	37	—
(Decrease) increase in cash and cash equivalents	7,523	(2,051)	(19,844)
Cash and cash equivalents at beginning of period	23,726	25,777	45,621
Cash and cash equivalents at end of period	$31,249	$23,726	$25,777
Supplemental non-cash activities:			
Cashless exercise of stock options and shares surrendered upon restricted stock vesting	$—	$—	$(61)
Fair value of warrants issued	$1,857	$4,055	$—
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$218	$908	$—

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2013, 2012, and 2011

(1) Description of Business

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan HDS)—is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic 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 for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe.

In the United States, the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States.

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 the first half of 2015, but anticipates that additional working capital will 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 and clinical trial results; 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 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.

(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, impairment of long-lived assets, 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.

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DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ending December 31, 2013, 2012, and 2011

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. As of December 31, 2013, three customers individually accounted for greater than 10% of the Accounts Receivable balance.

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.

Prior to obtaining authorization to affix the CE Mark to its Generation Two CHEMOSAT system in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of December 31, 2013 includes finished goods and components relating to Generation Two of the CHEMOSAT 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, 2013 and 2012, the Company did not have any derivative instruments that were designated as hedges.

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 for product sales to a distributor. 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. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied. The Company recognized deferred revenue related to a research and distribution agreement upon the completion of certain requirements under the agreement.

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. As of December 31, 2013, four customers individually accounted for greater than 10% of product revenue.

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 fees, 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.

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. 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 13 for additional information.

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Net Loss per Common Share
Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the years ended December 31, 2013, 2012 and 2011 are as follows:

(in thousands, except share data)	2013	2012	2011
Net loss – basic	$(30,324)	$(51,868)	$(30,885)
Adjust for gain on warrant derivative liability	(1,835)	—	—
Net loss - diluted	(32,159)	(51,868)	(30,885)
Net loss per share – basic	(0.30)	(0.85)	(0.68)
Weighted average shares outstanding – basic	100,809,824	61,275,527	45,236,921
Warrant exercises	4,294,353	—	—
Weighted average shares outstanding – diluted	105,104,177	61,275,527	45,236,921
Net loss per share – diluted	(0.31)	(0.85)	(0.68)

For the years ended December 31, 2013, 2012, and 2011 the following potentially dilutive securities 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:

	2013	2012	2011
Stock options	4,035,143	4,788,887	4,129,749
Unvested restricted shares	325,722	501,468	193,532
Warrants	9,432,000	5,642,580	2,512,934
Total	13,792,865	10,932,935	6,836,215

Segment Information
The Company currently operates in one business segment, which is the development and commercialization of the CHEMOSAT/Melphalan HDS system. A single management team that reports to the Co-Chief Executive Officers comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Foreign Currency and Currency Translation
Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statement of operations.

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The assets and liabilities of the Company's international subsidiaries are translated from their functional currencies into United States dollars at exchange rates prevailing at the balance sheet date. Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising from translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

Recently Adopted Accounting Pronouncements
In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02 which requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires an entity to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. This guidance is effective for reporting periods beginning after December 15, 2012. The Company adopted this guidance effective January 1, 2013. The Company's adoption of this standard did not have a material impact on its consolidated financial statements.

In March 2013, the FASB issued ASU 2013-05, which permits an entity to release cumulative translation adjustments into net income when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. Accordingly, the cumulative translation adjustment should be released into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided, or, if a controlling financial interest is no longer held. The revised standard is effective for fiscal years beginning after December 15, 2013; however, early adoption is permitted. The Company does not expect adoption of this ASU to materially impact its consolidated financial statements.

(4) Inventories

Inventories consist of:

(in thousands)	December 31, 2013	December 31, 2012
Raw materials	$ 249	$ 197
Work-in-process	364	405
Finished goods	106	503
Total inventory	$ 719	$ 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 CHEMOSAT system in April 2012, including components used in the kits sold during the year ended December 31, 2013. As a result, some of the costs of sales related to recognized and deferred revenue was expensed in earlier periods.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(in thousands)	December 31, 2013	December 31, 2012
Insurance premiums	$ 407	$ 232
Professional fees	377	531
Income tax credits receivable	326	305
Kits for clinical use	287	81
Other[1]	314	308
Total prepaid and other current assets	$ 1,711	$ 1,457

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaids and other current assets at December 31, 2013 and 2012.

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(6) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	December 31, 2013	December 31, 2012
Leaseholds	$ 1,749	$ 1,716
Furniture	957	952
Equipment	1,552	1,473
Computers	2,143	2,141
Buildings and land	603	603
	7,004	6,885
Accumulated depreciation	(3,935)	(2,843)
	$ 3,069	$ 4,042

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was $1.1 million, $1.3 million, and $1.0 million, respectively.

(7) Current Accrued Expenses

Current accrued expenses include the following:

(in thousands)	December 31, 2013	December 31, 2012
Compensation, excluding taxes	$ 1,866	$ 1,933
Deferred rent	485	443
Professional fees	360	1,438
Contract Research Organization	—	1,283
Other[1]	1,029	693
Total accrued liabilities	$ 3,740	$ 5,790

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2013 and 2012.

(8) Restructuring Expenses

During the year ended December 31, 2013, the Company implemented restructurings of its workforce to better focus the Company's organizational structure, increase efficiency and concentrate financial resources on its clinical development program and European commercialization activity. This resulted in a reduction in the Company's workforce by 50 employees. As a result of termination benefits given to the impacted employees, the Company incurred a total cost of approximately $4.0 million which is included on the Consolidated Statements of Operations in both Selling, general and administrative expenses and Research and development expenses, as appropriate. Accrued severance expense at December 31, 2013 of $1.6 million is included in current accrued expenses and $0.4 million is included in long-term accrued expenses on the Consolidated Balance Sheets, for a total accrued severance expense of $2.0 million at December 31, 2013.

(in thousands)	December 31, 2013
Severance and restructuring expenses	$ 3,974
Restructuring expenses paid by December 31, 2013	(1,955)
Total restructuring expenses accrued as of December 31, 2013	$ 2,019

In November 2013, the Board of Directors approved an employee retention program for certain of its key employees, including the Company's executive officers. The executive officers of the Company will be eligible to receive a cash retention bonus payment equal to fifty percent (50%) of their current annual salary if the executive officer remains employed by the Company through March 31, 2015. The expense related to this program is being accrued on a quarterly basis as the services are rendered and is included in current accrued expenses on the Consolidated Balance Sheets and Operations in both Selling, general and administrative expenses and Research and development expenses on the Consolidated Statements of Operations.

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(9) Assets and Liabilities Measured at Fair Value

Derivative Financial Instruments
As disclosed in Note 10, 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
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, 2013 and 2012, 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)	2013	2012	2013	2012	2013	2012	2013	2012
Assets								
Money market funds	$1,956	$1,967	—	—	—	—	$1,956	$1,967
Liabilities								
Derivative instrument liabilities	—	—	—	—	$2,310	$3,427	$2,310	$3,427

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
(in thousands)	Derivative
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
Total change in the fair value of the liability included in earnings	(2,756)
Fair value of warrants issued and exercised	1,639
Balance at December 31, 2013	$ 2,310

(10) Stockholders' Equity

Stock Issuances

In June 2009, the Company completed the sale of 0.9 million shares of its common stock and the issuance of warrants to purchase 1.0 million 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 October 2013 sale of common stock and warrants. At December 31, 2013, the 2009 Warrants were exercisable at $0.16 per share with 1.0 million 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 July 2011, the Company completed the sale of 5.0 million 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.

In December 2011, the Company entered into a sales agreement (the “December 2011 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.

In May 2012, the Company completed the sale of 15.3 million shares of its common stock and the issuance of warrants to purchase 4.6 million 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. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company’s October 2013 sale of common stock and warrants. At December 31, 2013, the 2012 Warrants were exercisable at $0.16 per share with 4.4 million 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 December 2012, the Company entered into a Common Stock Purchase Agreement (Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin) for a committed equity financing facility (CEFF) program. The Purchase Agreement provides that Terrapin is committed to purchase up to $35.0 million of our common stock over the 24-month term of the Purchase Agreement. During the year ended December 31, 2013 the Company sold approximately 5.6 million shares of its common stock through the program. The Company received proceeds of approximately $9.0 million, with net cash proceeds after related expenses from this transaction of approximately $8.9 million. The shares were issued pursuant to registration statement on Form S-3. 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. In addition to the $9.0 million raised during the year ended December 31, 2013, the Company previously raised $2.1 million under the CEFF program. As a result, there was approximately $23.9 million available under this CEFF program as of December 31, 2013.

During the three months ended March 31, 2013, the Company sold approximately 14.2 million shares of its common stock under the December 2011 Sales Agreement with Cowen and Company, LLC for proceeds of approximately $20.9 million, with net cash proceeds after related expenses of approximately $20.8 million, successfully completing the program. There are no shares of common stock of the Company remaining for sale under the December 2011 Sales Agreement.

On March 13, 2013, the Company entered into a new sales agreement (the “March 2013 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 $50,000,000, from time to time, through an “at the market” equity offering program under which Cowen and Company, LLC will act as sales agent. During the year ended December 31, 2013, the Company sold approximately 16.4 million shares of its common stock under the March 2013 Sales Agreement with Cowen and Company, LLC for proceeds of approximately $5.0 million, with net cash proceeds after related expenses of approximately $4.8 million. The shares were issued pursuant to registration statement Form S-3 (333-187230). 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.

In October 2013, the Company completed the sale of 21.0 million shares of its common stock and the issuance of warrants to purchase 9.4 million common shares (the "2013 Warrants") pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 Warrants. The 2013 Warrants will become exercisable at $0.44 per share on April 30, 2014. The 2013 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

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.

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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 2013, 2012, and 2011 is as follows:

	Number of Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
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	
Outstanding at December 31, 2012	4,788,887	$1.23-15.54	$ 4.79	6.88
Granted	2,085,717	0.30-2.13	1.09	
Expired	(270,000)	1.23-1.87	1.53	
Forfeited	(2,569,461)	0.38-12.34	3.97	
Outstanding at December 31, 2013	4,035,143	$0.30-15.54	$ 3.62	2.13
Exercisable at December 31, 2013	2,136,785	$1.24-15.54	$ 5.68	5.56

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, 2013, 2012 and 2011:

	Year Ended December 31,		
	2013	2012	2011
Weighted average risk-free interest rate	1.30 %	1.11 %	2.07 %
Weighted average expected volatility	92.31 %	79.89 %	74.64 %
Expected volatility	86.16-97.21%	77.37-84.81%	73.88% - 79.11 %
Dividend yield	0.00 %	0.00 %	0.00 %
Weighted average expected option term (in years)	5.66	6.17	6.00
Weighted average grant date fair value	$0.81	$2.59	$3.79

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 2013 and 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.

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A summary of the Company's non-vested options to purchase shares as of December 31, 2013 and changes during the year ended December 31, 2013 and December 31, 2012 are presented below:

	Non-Vested Options	
	Number of Options	Weighted Average Exercise Price
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
Granted	2,085,717	1.09
Vested	(686,232)	5.38
Forfeited	(1,184,479)	3.37
Non-vested at December 31, 2013	1,898,358	1.30

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

	2013	2012	2011
Selling, general and administrative	$0.2	$1.7	$2.2
Research and development	0.0	1.1	1.4
Total	$0.2	$2.8	$3.6

Additional compensation expense of $0.6 million, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 1.25 years.

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2013 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 $0.26 as of December 31, 2013, 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, 2013 and changes during the year ended December 31, 2013 and December 31, 2012 are presented below:

	Restricted Stock Activity	
	Number of Shares	Weighted Average Grant Date Fair Value
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
Granted	276,250	0.42
Vested	(313,395)	2.57
Forfeited	(138,601)	4.32
Non-vested at December 31, 2013	325,722	$ 1.05

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

	2013	2012	2011
Selling, general and administrative	$0.2	$0.7	$0.5
Research and development	0.0	0.3	0.1
Total	$0.2	$1.0	$0.6

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Additional compensation expense of $0.1 million relating to the unvested portion of restricted stock granted, is expected to be recognized over a remaining average period of 0.7 years.

Warrants

The Company allocated part of the proceeds of public offerings in 2009, 2012 and 2013 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 of December 31, 2013, the 2009, 2012 and 2013 Warrants are classified as derivative instrument liabilities.

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, 2013, the Company recorded pre-tax derivative instrument income of $2.8 million. The resulting derivative instrument liabilities totaled $2.3 million at December 31, 2013. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2013 was determined by using an option pricing model assuming the following:

	2013 Warrants		2012 Warrants		2009 Warrants	
Expected volatility	90.75	%	106.77	%	128.50	%
Risk-free interest rates	1.63	%	0.26	%	0.10	%
Expected life (in years)	4.83		1.41		0.45	

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, 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
Issued	9,432,000	0.44	0.44	
Exercised	(202,689)	1.20	1.20	
Expired	–			
Outstanding at December 31, 2013	14,871,891	$0.16-0.44	$ 0.34	3.51

(11)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, 2013, the Company had not used any of the available funds.

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(12) 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 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, 2013 conversion rate): Year 1 – €106,051 ($146,009), Year 2 – €134,974 ($185,830), Year 3 – €159,077 ($219,015) and Years 4 and 5 – €183,179 ($252,198). 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.

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 in November 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.

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.

Future minimum lease payments under all operating leases at December 31, 2013 are as follows:

(in thousands)	Future Lease Payment
2014	$ 1,469
2015	1,338
2016	1,183
2017	1,052
2018	1,091
	$ 6,133

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Rent expense totaled approximately $1.5 million, $1.5 million and $1.2 million, for the years ended December 31, 2013, 2012 and 2011, 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, 2015 if not renewed by the Company.

(13) 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)	2013	2012	2011
Income taxes using U.S. federal statutory rate	$(10,309)	$(17,621)	$(10,501)
Amortization of gain on IP migration	781	754	–
State income taxes, net of federal benefit	(1,390)	(4,299)	(3,418)
Foreign rate differential	2,761	3,716	52
Valuation allowance	7,683	17,561	20,563
Derivative charge	(937)	(734)	(5,292)
Stock option exercises and cancellations	1,589	310	102
Research and development credits	(1,090)	326	(1,633)
Other	912	(13)	127
Total	$–	$–	$–

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

(in thousands)	2013	2012
Deferred tax assets:		
Employee compensation accruals	$4,077	$6,176
Accrued liabilities	870	299
Research tax credits	3,472	2,382
Other	79	31
Net operating losses	71,874	63,765
Total deferred tax assets	80,372	72,653
Deferred tax liability:		
Total deferred tax liabilities	–	–
Valuation allowance	80,372	72,653
Net deferred tax assets	$–	$–

As of December 31, 2013 and December 31, 2012, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $158.4 million and $138.1 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 $152.3 million is available to offset future federal taxable income which will expire between 2018 and 2033. As of December 31, 2013 and December 31, 2012, the Company had net operating loss carryforwards for state and city income tax purposes of approximately $268.8 million and $231.0 million, respectively, which expire through 2033. As of December 31, 2013 and December 31, 2012, the Company had a net operating loss carryforward for foreign income tax purposes of $19.0 million and $17.4 million, respectively, which have indefinite carryforward periods.

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 $7.7 million, $17.6 million, $20.5 million, $15.0 million, and $5.9 million in 2013, 2012, 2011, 2010, and 2009, respectively.

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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., as well as various state and international 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 Company's New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company's tax years generally remain open to examination for all federal, state and foreign tax matters until its net operating loss carryforwards are utilized and the applicable statutes of limitation have expired. The 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.

(14) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2013 and 2012.

	2013 Quarters Ended			
(in thousands except per share amounts)	March 31	June 30	September 30	December 31
Operating loss	$(10,202)	(10,587)	(6,702)	(5,526)
Change in fair value of warrant liability, net	(2,272)	5,115	(497)	410
Net loss	(12,845)	(5,482)	(7,206)	(4,792)
Basic and diluted loss per share	(0.15)	(0.06)	(0.07)	(0.04)

	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)

(15) Subsequent Events

During the first quarter through February 28, 2014, the Company sold approximately 16.0 million shares of our common stock under the Sales Agreement through an "at the market" equity offering program for net proceeds of approximately $4.4 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. As of March 11, 2014, the Company has approximately $40.4 million remaining under the program, assuming sufficient shares are available to be issued.

The Company held a Special Meeting of Stockholders on February 24, 2014. The proposal to approve an amendment to Delcath's Amended and Restated Certificate of Incorporation to effect a reverse stock split of its Common Stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014 and to grant authorization to the Board of Directors to determine, in its discretion, whether to implement the reverse stock split, as well as its specific timing and ratio, was approved by shareholders.

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.

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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 interim Co-Chief Executive Officers, 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 interim Co-Chief Executive Officers concluded that the Company's disclosure controls and procedures as of December 31, 2013 (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 interim Co-Chief Executive Officers, 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, 2013 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, 2013. 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, 2013, the Company's internal control over financial reporting was effective based on those criteria.

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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 2014 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.

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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, 2013 and 2012

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012, and 2011

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012, and 2011

Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012, and 2011

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.

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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/ Graham G. Miao	/s/ Jennifer K. Simpson
Graham G. Miao, Ph.D.	Jennifer K. Simpson
Interim Co-President and Co-Chief Executive Officer, Chief Financial Officer (Co-Principal Executive Officer and Principal Financial Officer)	Interim Co-President and Co-Chief Executive Officer, Global Head of Business Operations (Co-Principal Executive Officer)
Dated: March 12, 2014	Dated: March 12, 2014

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/ Graham G. Miao Graham G. Miao, Ph.D.	Interim Co-President and Co-Chief Executive Officer, Chief Financial Officer (Co-Principal Executive Officer and Principal Financial Officer)	March 12, 2014
/s/ Jennifer K. Simpson Jennifer K. Simpson	Interim Co-President and Co-Chief Executive Officer, Global Head of Business Operations (Co-Principal Executive Officer)	March 12, 2014
/s/ Barbra C. Keck Barbra C. Keck	VP, Controller (Principal Accounting Officer)	March 12 , 2014
/s/ Gabriel Leung Gabriel Leung	Chairman of the Board	March 12, 2014
/s/ Laura Brege Laura Brege	Director	March 12, 2014
/s/ Anastasios Konidaris Anastasios Konidaris	Director	March 12, 2014
/s/ Harold S. Koplewocz Harold S. Koplewicz, M.D.	Director	March 12, 2014
/s/ Laura Philips	Director	

Laura Philips, Ph.D.		March 12, 2014
/s/ Roger Stoll Roger Stoll, Ph.D.	Director	March 12, 2014
/s/ Douglas Watson Douglas Watson	Director	March 12, 2014

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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 (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 (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)).
4.4		Form of Warrant to Purchase Shares of Common Stock dated October 28, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed October 23, 2013 (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		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)).
10.7	*	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)).

10.8	*	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)).

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10.9	*	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)).
10.10	*	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)).
10.11		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)).
10.12		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)).
10.13		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)).
10.14	*	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)).
10.15		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)).
10.16		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)).
10.17	†	License, Supply and Contract Manufacturing Agreement between Synerx Pharma, LLC and Bioniche Teoranta and the Company dated as of October 13, 2010.
10.18	*	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)).
10.19		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)).
10.20		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)).
10.21	*	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)).

10.22	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)).

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10.23		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)).
10.24	*	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)).
10.25	*	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)).
10.26	*	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)).
10.27	*	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)).
10.28		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)).
10.29		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)).
10.30	*	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)).
10.31		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)).
10.32		Loan and Security Agreement dated April 20, 2012 between Silicon Valley Bank and Delcath Systems, Inc. (incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 (Commission File No. 001-16133)).
10.33		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))
10.34		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))
10.35		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))
10.36		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))
10.37		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))
10.38	*	Form of Executive Security Agreement (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed December 20, 2013 (Commission File No. 001-16133))

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23.1	**	Consent of Ernst & Young LLP
31.1	**	Certification by Co-Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Co-Principal executive officer Pursuant to Rule 13a 14.
31.3	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	**	Certification of Co-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 Co-Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.3	**	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.