DELCATH SYSTEMS, INC.
Form 10-K
March 29, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2016
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.)
1633 Broadway, Suite 22C 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:

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

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 No

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

Yes No

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 No

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 No

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.

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		Accelerated filer
Non-accelerated filer	(Do not check if smaller reporting company)	Smaller reporting company

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

Yes No

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 $4.00 per share, was $5,973,172 as of June 30, 2016.

At March 28, 2017, the registrant had outstanding 113,457,971 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2017 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, 2016 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, 2016 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 Securities Exchange Act of 1934, as amended (Exchange Act) and Section 27A of the Securities Act of 1933, as amended (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, 2016 in Item 1A under "Risk Factors" as well as in Item 7A "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;
- our ability to successfully commercialize CHEMOSAT/Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and system;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT/Melphalan/HDS;
- 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 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100.

Company Overview

Delcath Systems, Inc. is an interventional oncology Company focused on the treatment of primary and metastatic liver cancers. Our investigational 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 systemic exposure and associated side effects. In Europe, our system is in commercial development under the trade name

Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT®), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our primary research focus is on ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of: The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, a Global Phase 3 clinical trial that is investigating overall survival in mOM, and a Global Phase 2 clinical trial program investigating Melphalan/HDS with and without sorafenib in HCC and Melphalan/HDS in ICC. The Company recently announced a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the

design of a pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma. Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC).

The direction and focus of our CDP for CHEMOSAT/Melphalan/HDS is informed by prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and United States regulatory activity has led to the implementation of several safety improvements to our product and the associated medical procedure.

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, HCC and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing adequate reimbursement for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT/Melphalan/HDS represents a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver. We believe that CHEMOSAT/Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Cancers in the Liver – A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to GLOBOCAN and American Cancer Society (ACS) Facts & Figures 2008, approximately 1.2 million patients globally are diagnosed each year with primary liver cancer or cancer that has metastasized to the liver. 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 overall costs of cancer in 2008 were $201 billion: $77 billion for direct medical costs (total of all health expenditures) and $124 billion for indirect mortality costs (cost of lost productivity due to premature death). The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death. Patient prognosis is generally poor once cancer has spread to the liver.

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 or ICC) 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.

Ocular Melanoma

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. We estimate that up to 4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, we estimate that approximately 90% of patients will develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care (SOC) for patients with ocular melanoma liver metastases. As a

result, we estimate that approximately 2,000 patients with ocular melanoma liver metastases in the United States and Europe may be eligible for treatment with the Melphalan/HDS.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers – including HCC and ICC – are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. Approximately 90% of these patients are diagnosed with HCC. Excluding patients who are eligible for surgical resection or certain focal treatments, we estimate that approximately 15,000 patients with HCC in the United States and Europe may be eligible for treatment with Melphalan/HDS. We estimate that an additional 9,300 patients diagnosed with ICC may also be eligible for treatment with Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients in the United States 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. 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 primary liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society's 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 for surgery or for Transcatheter arterial chemoembolization, also known as TACE, the only currently 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 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.

Based on third party research, we estimate that up to 15,000 of the 65,000 patients diagnosed annually in the United States and Europe could be eligible candidates for treatment with the Melphalan/HDS. The FDA has granted orphan drug status to the Melphalan/HDS for treatment of patients with unresectable HCC. We believe that there is a large unmet medical need in first line therapy for patients with HCC, with Sorafenib the only currently approved systemic therapy in the United States, Europe and certain Asian markets.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the United States and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care. Based on third party research, we believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. We estimate that approximately 9,300 ICC patients in the United States and Europe annually could be candidates for treatment with Melphalan/HDS, which we believe represents a

significant market opportunity. We intend to pursue an orphan drug designation from the FDA for Melphalan/HDS for the treatment of patients with ICC.

About CHEMOSAT/Melphalan/HDS

CHEMOSAT/Melphalan/HDS administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP® therapy), 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 our proprietary filters. The filters absorb 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.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT/Melphalan/HDS is repeatable, and a new disposable CHEMOSAT/Melphalan/HDS is used for each treatment. Patients treated in both clinical and non-clinical settings have received up to 7 treatments. In the United States, melphalan hydrochloride for injection will be included with the system. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Risks associated with the CHEMOSAT/Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/Melphalan/HDS is associated with toxic side effects and certain risks, some of which are potentially life threatening. An integrated safety population comprised of patients treated during our prior clinical development using early versions of the Melphalan/HDS showed these risks to include grade 3 or 4 bone marrow suppression and febrile neutropenia, as well as risks of hepatic injury, severe hemorrhage, gastrointestinal perforation, stroke, and myocardial infarction in the setting of an incomplete cardiac risk assessment. In this integrated safety population, deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments.

Procedure and Product Refinements

The trials that comprised this integrated safety population used early versions of the device and procedure. As a consequence of these identified risks and experience gained in non-clinical, commercial usage in Europe, we have continued to develop and refine both the CHEMOSAT/Melphalan/HDS and the PHP procedure. The procedure refinements have included modifications to the pre, peri and post procedure patient management and monitoring, as well as the use of the following: prophylactic administration of proton pump inhibitors, prophylactic platelet transfusions, prophylactic hydration at key pre-treatment intervals, use of vasopressor agents coupled with continuous monitoring for maintenance of blood pressure and prophylactic administration of growth factors to reduce risk of serious myelosuppression. In addition, in 2012 we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other product enhancements.

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT/Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2016, physicians in Europe and the United States also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

Prior Clinical Development

Our Phase 3 clinical trial and multi-arm Phase 2 clinical trial of the Melphalan/HDS 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, we 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, 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 PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, we announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan/HDS 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 (hPFS). An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization and the European Society of Medical Oncology in September 2011. Data submitted in October 2012 to the FDA in Delcath's New Drug Application (NDA) comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the PHP arm 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 BAC arm, with 50% reduction in the risk of progression and/or death in the PHP treatment arm compared to the BAC control arm. Results of this study were published in Annals of Surgical Oncology, a prestigious medical journal in December 2015.

Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

Also in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using an early version of the Melphalan/HDS in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), ocular or cutaneous melanoma, metastatic colorectal adenocarcinoma (mCRC), and HCC. 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 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.

Phase 2 Multi-Histology Clinical Trial - HCC Cohort

In the HCC cohort (n=8) of our Phase 2 Multi-Histology trial, 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 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. We believe these results constitute a promising signal that warrants further clinical investigation.

Prior United States Regulatory Experience

Based on the results from our prior clinical development in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food 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, and subsequently amended the indication to ocular melanoma metastatic to the liver. Data submitted to the Food and Drug

Administration (FDA) used the early clinical trial versions of the system along with early clinical procedure techniques. Our NDA was accepted for filing by the FDA on October 15, 2012, and was designated for standard review with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

On May 2, 2013 we announced that an Oncologic Drug Advisory Committee (ODAC) panel convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of Melphalan/HDS did not outweigh the risks associated with the procedure. 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. 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. We believe that the protocol amendments and other procedure refinements instituted during clinical trials and subsequently in commercial, non-clinical usage in Europe, 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 in our current CDP.

Briefing materials presented to the 2013 ODAC panel by both the FDA and Delcath are available on our website at http://delcath.com/clinical-bibliography.

2013 Complete Response Letter

In September 2013 the FDA issued a complete response letter (CRL) in response to our NDA. The FDA issues a CRL after the review of a file has been completed and questions remain that preclude 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 Melphalan/HDS using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks." The FDA also required that the additional clinical trial(s) be conducted using the product the Company intends to market, and that certain clinical, clinical pharmacology, human factors and product quality elements of the CRL be addressed.

In January 2016, we announced the conclusion of a SPA with the FDA on the design of a new Phase 3 clinical trial of Melphalan/HDS to treat patients with hepatic dominant ocular melanoma. This SPA provides agreement that our new Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. The SPA agreement also represents the satisfactory resolution of a substantial number of the FDA’s CRL non-clinical trial related requirements.

Current Clinical Development Program

The focus of our current CDP is to generate clinical data for the CHEMOSAT/Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT/Melphalan/HDS and to the PHP procedure have addressed the severe toxicity and procedure-related risks observed during the previous Phase 2 and 3 clinical trials. The CDP is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals in various jurisdictions, including the United States.

FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the FOCUS Trial) - NCT02678572

In January 2016, we initiated a new pivotal Phase 3 OS clinical trial in hepatic dominant ocular melanoma with the first patient enrolled in February 2016. Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety, efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial's treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

The FOCUS Trial is being conducted at leading cancer centers in the United States and Europe. The Moffitt Cancer Center in Tampa, Florida was activated as a participating center in January 2016 with Jonathan Zager, M.D., FACS, Professor of Surgery in the Cutaneous Oncology and Sarcoma Departments and a Senior Member at Moffitt Cancer Center, serving as the trial's principal investigator. In October 2016 we announced the addition of several prestigious cancer centers in the United States and Europe. We intend to include approximately 30-40 leading cancer centers in the United States and Europe in the FOCUS Trial.

The FOCUS Trial is being conducted under a SPA we concluded with the FDA in January 2016. Under the terms of the SPA, the FOCUS Trial is the only Phase 3 trial required for submission of an NDA.

There currently is no SOC for the treatment of hepatic dominant ocular melanoma. The Melphalan/HDS has been granted orphan drug status by FDA for treatment of patients with ocular melanoma. Based on the strength of the efficacy data in this disease observed in our prior Phase 3 clinical trial and the reports of an improved safety profile observed in non-clinical trial experience in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL. We believe that ocular melanoma liver metastases represent a significant unmet medical need, and that pursuit of an indication in this disease state represents the fastest path to potential approval of the Melphalan/HDS in the United States.

Phase 2 Hepatocellular Carcinoma (HCC) & Intrahepatic Cholangiocarcinoma (ICC) Program

In 2014 we initiated a Phase 2 clinical trial program in Europe and the United States, with the goal of obtaining an efficacy and safety signal for Melphalan/HDS in the treatment of HCC and ICC. Due to differences in treatment practice patterns between Europe and the United States, we established separate European and United States trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

Protocol 201 NCT02406508 – Conducted in the United States, this trial is intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. The trial will evaluate overall response rate via modified Response Evaluation Criteria in Solid Tumors (mRECIST), progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life

Protocol 202 NCT02415036 – Conducted in Europe, this trial is intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial will also evaluate overall response rate via mRECIST criteria, progression

free survival, characterize the systemic exposure of melphalan and assess patient quality of life. Hospitals in Germany, Italy and the United Kingdom are participating in this trial.

ICC Cohort – In 2015 we expanded Protocol 202 to include a cohort of patients with ICC. The trial for this cohort is being conducted at the same centers participating in the Phase 2 HCC trial. Patient treatment and data collection for the ICC cohort is ongoing, and we will announce results for this cohort once the data are fully mature.

ICC Retrospective Data Collection - The original goal to obtain an efficacy signal for the Phase 2 ICC cohort has been satisfied by the result of multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These promising outcomes and observations were discussed with Key Opinion Leaders (KOL) at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP® therapy does, indeed, "demonstrate an efficacy signal in ICC and is worthy of full clinical investigation." Data from this retrospective data collection is being submitted for publication, and details of these findings will be announced when publically available.

In February 2017 we presented a summary of European investigator findings and our clinical development plans for ICC to the Cholangiocarcinoma Foundation's medical advisory board at the organization’s 2017 Annual Meeting. We recently announced a SPA agreement with the FDA for the design of a pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma.

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. These trials are actively enrolling, but 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.

A substantial portion of the Company’s operating expenses consist of research and development expenses incurred in connection with its clinical trials. See the Company’s Consolidated Financial included in Item 8 of this Annual Report on Form 10-K.

European Investigator Initiated Trials

In addition to the clinical trials in our CDP, we are supporting data generation in other areas. We are currently conducting two Investigator Initiated Trials (IITs) in Europe– one in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in the Netherlands, and another in HCC at Goethe University Hospital in Frankfurt, Germany. Both of these trials have opened for enrollment. We continue to evaluate other IITs as suitable opportunities present in Europe. We believe IITs will serve to build clinical experience at key cancer centers, and will help support efforts to obtain full reimbursement in Europe.

European Clinical Data Generation

On April 2, 2015 we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry will gather

data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe. Cancer centers in Germany, the United Kingdom, and the Netherlands are participating in the registry and patient enrollment has begun.

Recent Data Presentations

In September 2016, we announced that data from two studies supporting CHEMOSAT were presented at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) annual meeting. The first study, “Secondary Resectability of Ocular Melanoma Liver Metastases (OMLM) Following Percutaneous Hepatic Perfusion (PFP)” by M. Zeile, et al. of the Asklepios Barmbek Clinic in Hamburg, Germany, evaluated 7 patients with unresectable ocular melanoma liver metastases treated with CHEMOSAT. There were 12 CHEMOSAT procedures administered in total, with a median of 2 cycles per patient, and a range of 1 to 3. The objective response rate after 1-2 treatments was 71.4%. Two patients showed secondary resectability on imaging after completing two treatments and remain alive for over 26 months following resections. Progression free survival was 9.9 months and hepatic progression free survival was 11.2 months. Median survival for the study has not yet been reached, but is higher than 16.9 months. There were no adverse events of grade 3 or higher. Investigators concluded that CHEMOSAT is safe to use in these patients and that significant downsizing of ocular melanoma liver metastases can be achieved with CHEMOSAT. These researchers concluded that if these promising results were further validated it “may lead to a new standard of therapy for the treatment of patients with ocular melanoma liver metastases.”

The second study, “Percutaneous Isolated Hepatic Perfusion (Chemosaturation) In Patients With Primary Or Secondary Liver Tumours: Experience In 20 Patients”, by S. Marquardt et al., of Hanover Medical School in Hanover, Germany, retrospectively evaluated patients with advanced disease from primary or metastatic cancers of the liver. The local response rate (stable disease or partial response) was 80%. Mean progression free survival was 3.2 months. The investigators reported no major complications and that bone marrow suppression was common but controllable. The investigators concluded that patients with primary or secondary liver tumors that have disease progression under standard therapy “may profit from PHP with Melphalan,” that technical execution is problem-free, and complications are manageable.

In October 2016, we announced that a review of research conducted with CHEMOSAT has been accepted for publication by the prestigious medical journal, Advances in Therapy. The retrospective study, "Chemosaturation Percutaneous Hepatic Perfusion: A Systemic Review," was conducted by a team led by Dr. Arndt Vogel of the University of Hanover in Germany, and resulted from a CHEMOSAT Experts Forum convened by Delcath in February 2015. The study is expected to be published in early 2017. In July 2016, we announced that a review of clinical research treatment outcomes using Melphalan/HDS in patients with hepatic metastases has been accepted for publication in the prestigious journal, Cancer Control. Results of the study, "Chemosaturation with Percutaneous Hepatic Perfusion in Patients with Unresectable Hepatic Metastases: Review of Outcomes," by Evan S. Glazer, M.D., Ph.D. and Jonathan S. Zager, M.D., FACS of Moffitt Cancer Center, were published in the January 2017 edition of Cancer Control.

In February 2017, we announced that the American Journal of Clinical Oncology published a single-center retrospective review, in which authors found that investigational PHP with Melphalan/HDS offers promising results with a doubling of overall survival and significantly longer progression-free survival (PFS) and hPFS than other targeted therapies. The review, “Hepatic Progression-free and Overall Survival After Regional Therapy to the Liver for Metastatic Melanoma,” was written by a team from the Moffitt Cancer Center who analyzed clinical outcomes of three different non-randomized approaches used to treat 30 patients with liver metastases primarily resulting from ocular melanoma and skin melanoma. A third of the patients received PHP using melphalan delivered via the Delcath Hepatic Delivery System (Melphalan/HDS), 12 received chemoembolization (CE) and six received radioembolization with yttrium-90 (Y90). Two patients crossed over once their cancer progressed – one from PHP to Y90 and one from CE to PHP.

The paper’s authors concluded that patients who received PHP with Melphalan/HDS had significantly longer median hPFS at 361 days compared to 54 days for Y90 and 80 days for CE, as well as a longer median PFS at 245 days compared to 54 days for Y90 and 52 days for CE. Median overall survival was also longest for PHP at 608 days compared to 295 days for Y90 and 265 days for CE. The authors noted that further studies, including a randomized controlled trial, would be needed to confirm whether clinically superior outcomes can be achieved with PHP compared to other liver-targeted treatments.

Side effects following all treatments were similar, with most complications recorded as anorexia, abdominal pain, fatigue and nausea. Laboratory irregularities, such as thrombocytopenia and abnormal liver function tests, were seen immediately after treatment in some patients, but returned to baseline within a few days.

Also in February 2017, we announced results of a retrospective, multicenter study presented at the Regional Cancer Therapies 12th International Symposium in an oral presentation titled, "Percutaneous Hepatic Perfusion for Unresectable Metastatic Ocular Melanoma to the Liver: A Multi-Institutional Report of Outcomes." This analysis demonstrated that 45.7 percent of patients with ocular melanoma that metastasized to the liver who underwent PHP using Melphalan/HDS experienced a complete or partial response. The study further showed that among those who responded to treatment, overall survival was projected to be more than three years. The analysis was conducted by teams from Moffitt Cancer Center in Tampa, Fla., and the University of Southampton in the United Kingdom. The presentation was led by Dr. Alexandra Gangi of the Moffitt Cancer Center.

The analysis reviewed outcomes of 49 patients treated between 2008 and 2016 with Melphalan/HDS at either the Moffitt Cancer Center or the University of Southampton. Patients underwent a total of 115 PHP treatments. The median number of treatments per patient was two, with patients receiving one-to-six treatments.

Hepatic response to PHP was evaluable in 46 patients, among whom 45.7 percent showed complete or partial response, and 37.0 percent had stable disease. Median overall survival was not reached, but was projected to be 657 days (1.8 years). Among patients with a complete or partial response, overall survival was projected to be 1,207 days. Most common side effects following treatment were anemia, thrombocytopenia and neutropenia.

Market Access & Commercial Clinical Adoption

European Union

Our immediate market access and clinical adoptions efforts continue to be 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. We also continue to support clinical adoption of CHEMOSAT in the Netherlands, Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since launching CHEMOSAT in Europe, treatments have been performed at over 20 leading European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, and cutaneous melanoma.

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. 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.

Germany

In October 2015, we announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a national Zusatzentgeld (ZE) reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group (DRG) code is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created, and will replace the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually for reimbursement of their CHEMOSAT treatment. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany.

In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually.

United Kingdom

In the United Kingdom, though Delcath and our participating cancer centers identified existing Healthcare Resource Groups (HRG) code(s), we have been advised that hospitals have not used it for coverage of CHEMOSAT related costs. We continue to work with the HRG organization that decides on new HRG codes toward receipt of a dedicated and permanent reimbursement code in the future.

Delcath expects to consult again with the Interventional Procedures Advisory Committee at the National Institute for Clinical Excellence (NICE) in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. This would enable greater scope for commercialization because it would allow more use by NHS clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement with the NHS.

In May 2014, the NICE, a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. NICE stated that this research may take the form of observational studies. With continued enrollment in the UK in our Phase 2 HCC and ICC trial in 2016, we believe the data generated from these studies will help provide supporting clinical data and address the concerns raised by NICE relative to survival, quality of life and adverse events. NICE may decide to conduct a Technology Appraisal of CHEMOSAT thereafter, the outcome of which could influence the long-term reimbursement status.

In the short term, public patients will continue to be treated in the UK through clinical trials. Private patients will continue to be treated through the established private treatment pathway such as private insurance coverage or self-pay.

Spain

In April 2016, we announced that the General and Digestive Surgery team at HM Sanchinarro University Hospital had activated the hospital's CHEMOSAT program. The Sanchinarro team successfully performed three procedures with CHEMOSAT, using the procedure to treat patients with peripheral cholangiocarcinoma, neuroendocrine tumors and colorectal liver metastases. HM Sanchinarro University Hospital is the second center in Spain to offer CHEMOSAT treatments.

Turkey

In April 2016 we announced the activation of the Hacettepe University Clinic in Ankara, Turkey as a CHEMOSAT treatment center. Hacettepe University Clinic successfully completed its first CHEMOSAT treatments in March 2016, and the center represents the first CHEMOSAT commercial location to be activated outside of the European Union. We believe that Hacettepe University can serve as an important hub for CHEMOSAT treatment to patients in Turkey and throughout the region.

Other European Markets

Permanent reimbursement coverage in remaining EU markets will require additional time to secure. For France, Spain and the Netherlands, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Phase 3 trial manuscript has been accepted for publication in the prestigious Annals of Surgical Oncology and will serve as the foundation for the reimbursement efforts in these countries. In the interim period, we are seeking payment through various avenues, including new technology programs.

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 will play a lesser role in its current commercial activities. In Spain, the Company has determined that there was no benefit to continuing with an indirect model and therefore terminated its relationship with its distributor in Spain and is now represented in Spain through a sales agency.

Regulatory Status

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.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath Melphalan/HDS 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, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, 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 IND, which must become effective before human clinical trials may begin and must be updated annually;

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

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

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the European Economic Area (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 1 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 4 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 4 clinical trials.

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

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which 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 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.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the 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) whose 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.

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 six 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 an orphan drug designation of the drug melphalan for the treatment of HCC. In July 2015, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of cholangiocarcinoma, which includes ICC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all or on a timely basis.

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.

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.

European Regulatory Environment

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 EU 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. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. 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

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.

CHEMOSAT 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.

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.

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 EU 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. We will continue to evaluate commercial opportunities in these and other markets when resources are available and at an appropriate time.

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 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 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.

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.

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.

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.

Manufacturing and Quality Assurance

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

We are 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, we announced that we had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, we announced that we 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 nine United States utility patents, one United States design patent, five pending United States utility patent applications, eleven issued foreign counterpart utility patents, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications (one of which has been allowed). We presently have issued utility and design patents with claims related to certain features of the current version of CHEMOSAT/Melphalan/HDS in the United States and Japan and a design patent protection in Argentina, Australia, Canada, China and Europe.

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 pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT/Melphalan/HDS that will enable us to expand our platform beyond the treatment of cancers in the liver. There can be no assurance that the 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. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

Certain of our United States and foreign patents have already expired and other patents relating to the CHEMOSAT/Melphalan/HDS 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 that provide 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 2016, Delcath added 7 employees to support clinical trial implementations in the EU and United States and to meet the demands of commercial sales. As of December 31, 2016, Delcath had 43 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Available Information

Delcath maintains a website at www.delcath.com. The Company makes available, free of charge on our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the

Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after the Company electronically files those reports with, or furnishes them to, the Securities and Exchange Commission, or the SEC. The Company is not including the information contained at www.delcath.com or at any other internet address as part of, or incorporating by reference into, this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks Related to Our Business and Financial Condition

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 Melphalan/HDS Kit system, which precludes approval of our existing NDA in its current form.

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 CRL with respect to our NDA seeking an indication for ocular melanoma liver metastases for our Melphalan/HDS Kit system. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude approval of the NDA in its current form. The FDA comments in the CRL included, but were not limited to, a statement that we must perform additional “well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS Kit using overall survival as the primary efficacy outcome measure” and which “demonstrates that the clinical benefits of Melphalan/HDS Kit outweigh its risks.” The FDA also requires that the additional clinical trial(s) be conducted using the product the company intends to market. Prior to conducting additional clinical trials, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors.

As a part of the regulatory process of obtaining marketing clearance for Melphalan/HDS, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. In 2014, we initiated a Phase 2 clinical trial for HCC in both the United States and Europe. In 2015, we expanded the Phase 2 clinical trial for HCC to include a cohort of patients with ICC. The trial for this cohort will be conducted at the same centers participating in the Phase 2 HCC trial. Additionally, in January 2016 we received agreement on a SPA from the FDA and have initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market's perception of this clinical data or FDA's perception of this clinical data, may adversely impact our ability to obtain approval, and the financial condition. Additionally, even if the results of our Phase 2 clinical trial for HCC and ICC are positive, there is

a substantial risk that it will fail to have positive results in Phase 3 clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm issued a report dated March 28, 2017 in connection with the audit of our financial statements as of December 31, 2016, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, our notes to our financial statements for the year ended December 31, 2016 included a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment.

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 CHEMOSAT/Melphalan/HDS and currently we have only developed this system for the treatment of cancers in the liver. If CHEMOSAT/Melphalan/HDS for the treatment of cancers in the liver fails as a commercial product, we have no other products to sell. In addition, since CHEMOSAT is currently only authorized for marketing in the EEA and limited other jurisdictions, if we are unsuccessful in commercializing the product in the EEA and if Melphalan/HDS 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 Melphalan/HDS. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude 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. CHEMOSAT/Melphalan/HDS 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, 2016, we had $4.4 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, 2016 and 2015, we incurred net losses of approximately $18.0 million and $14.7 million, respectively, and we expect to continue to incur losses in 2017. To date, we have funded our operations through a combination of private placements and public offerings of our securities, including convertible notes. 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 CHEMOSAT/Melphalan/HDS 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 further commercialize CHEMOSAT/Melphalan/HDS, complete our clinical trials or conduct future development and clinical trials.

We will require additional financing to complete our clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize our product in the EEA and any other markets where we receive approval for our system. 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 CHEMOSAT/Melphalan/HDS, obtain regulatory approvals or complete our development projects or our clinical trials.

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

- clinical studies, including a Phase 2 clinical trial to establish proof of concept in HCC and ICC and a Phase 3 clinical trial to investigate overall survival in ocular melanoma liver metastases;
- the timing and costs of our various United States 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.

Form S-3 limits the aggregate market value of securities that we are permitted to offer in any 12 month-period under Form S-3 to one-third of our public float. Our ability to raise capital may be impaired and we may not be able to utilize the Form S-3 to access the capital markets.

Insufficient funds may require us to curtail or stop our commercialization activities, regulatory 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.

CHEMOSAT/Melphalan/HDS 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. Melphalan/HDS 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 Melphalan/HDS, 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 Melphalan/HDS 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. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

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

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the PDUFA, 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 Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA issued a CRL. The FDA comments in the CRL included, but were not limited to, a statement that we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product the company intends to market. Prior to conducting additional clinical trials, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. However, even if we complete clinical trials and satisfy all the requirements of the CRL, we may not obtain regulatory approval from the FDA. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current version of CHEMOSAT/Melphalan/HDS 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 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 CHEMOSAT, our ability to commercialize CHEMOSAT in the EEA will be significantly limited.

In the EEA, CHEMOSAT 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 CHEMOSAT is limited to this approved indication. To the extent that our promotion of CHEMOSAT 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 CHEMOSAT in the EEA.

We are limited to marketing CHEMOSAT in the EEA as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT 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. Physicians intending to use our device must obtain melphalan separately for use with CHEMOSAT 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 2012, 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 Generation Two 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 Generation Two 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 CHEMOSAT/ Melphalan/HDS 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 (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 CHEMOSAT/Melphalan/HDS 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;
- 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 will take many years, require substantial resources and may never lead to the approval of Melphalan/HDS by the FDA for use in the United States.

We cannot sell or market Melphalan/HDS with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for Melphalan/HDS. 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 Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for Melphalan/HDS 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 Melphalan/HDS 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 for ocular melanoma liver metastases for our Melphalan/HDS. In September 2013, the FDA issued a CRL. The FDA comments in the CRL included a statement that we must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. Failure to obtain FDA approval will have a material adverse effect on our business, financial condition and results of operations.

Even if we obtain regulatory approval for the Melphalan/HDS in the United States, our ability to market the Melphalan/HDS 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 Melphalan/HDS, our ability to market and promote the Melphalan/HDS would be limited to the approved indication, so even with FDA approval, the Melphalan/HDS 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. 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 Melphalan/HDS, 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 Melphalan/HDS for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase 3 clinical trial of Melphalan/HDS in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of Melphalan/HDS in patients with primary and metastatic melanoma stratified into four arms.

In 2014, we initiated a Phase 2 clinical trial for HCC in both the United States and Europe. In 2015, we expanded the Phase 2 clinical trial for HCC to include a cohort of patients with ICC. Additionally, in January 2016 we received agreement on a SPA from the FDA and have initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases.

It may take several years to complete the testing of Melphalan/HDS for use in the treatment of these indications, 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 3 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 Melphalan/HDS for other indications. If we are unable to develop Melphalan/HDS 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 Melphalan/HDS in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT/ Melphalan/HDS and significantly reduce our ability to commercialize CHEMOSAT/ Melphalan/HDS.

We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT/Melphalan/HDS, 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 Melphalan/HDS, 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 rely upon third parties to conduct monitoring and data collection of our ongoing and future clinical trials, including our Phase 2 HCC clinical trial with an ICC cohort and our Phase 3 ocular melanoma trial. 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 Melphalan/HDS if these requirements are not met.

Purchasers of CHEMOSAT 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 CHEMOSAT in the EEA.

We have obtained the right to affix the CE Mark for CHEMOSAT, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell CHEMOSAT. In Germany, we have received a ZE diagnostic-related group code, which permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures beginning in 2016. Negotiations on the amount of reimbursement to be received under the code are currently underway and will continue through most of 2016. Consequently, reimbursement obtained may not be for the full amount sought. In countries where we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities

in those countries. In the United Kingdom, we began seeking a block fund grant in 2014. Ongoing changes to the process and funding streams have resulted in delays that made the award and timing of any block grant funding difficult to predict. Accordingly, we may not receive the grant in a timely manner or at all.

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. For example, throughout 2015, physicians and patients in Germany submitted and received approvals for Individual Funding Requests (IFRs) granting reimbursement for the treatment of liver metastases with CHEMOSAT. We expect that IFRs will continue to be the main reimbursement vehicle in the German market in 2016 until the ZE reimbursement is fully negotiated. 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 CHEMOSAT 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. Melphalan/HDS is currently not approved by the FDA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the use of Melphalan/HDS since the product is currently not approved outside the EEA. We will seek reimbursement by third-party payors of the cost of Melphalan/HDS 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 healthcare providers.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT/Melphalan/HDS and the demand for CHEMOSAT/Melphalan/HDS. 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 (ACA) were enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. The President and members have Congress have recently introduced legislative proposals to significantly alter the ACA. It is uncertain what consequences these proposals or the implementation of existing provisions will have on our efforts to commercialize CHEMOSAT/Melphalan/HDS.

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

The commercial success of CHEMOSAT/Melphalan/HDS will depend upon its acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT/Melphalan/HDS or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, and CHEMOSAT/Melphalan/HDS as effective and desirable, our efforts to market CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS and adversely impact our business, financial condition and results of operations.

Further, third-party payors may deny reimbursement if they determine that CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the CHEMOSAT/Melphalan/HDS

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, CHEMOSAT is approved for marketing as a device only, and doctors will separately obtain melphalan for use with CHEMOSAT. 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 CHEMOSAT. 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 CHEMOSAT/Melphalan/HDS from third parties, some of which are sole-source suppliers.

The components of CHEMOSAT/Melphalan/HDS, 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 CHEMOSAT/Melphalan/HDS are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If we 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 CHEMOSAT/Melphalan/HDS, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply CHEMOSAT/Melphalan/HDS to the market.

All of the manufacturers of the components for CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS could be jeopardized. CHEMOSAT/Melphalan/HDS 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 we rely on third-party vendors to perform the sterilization process. A third-party vendor's failure to properly sterilize a component may cause manufacturing or assembly delays.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize the Delcath system in the United States or complete our Phase 2 clinical trial for HCC and ICC in the United States, our global Phase 3 in ocular melanoma liver metastases or any future clinical trials.

We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC (Synerx) and Bioniche Teoranta (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 Phase 2 clinical trial for HCC and ICC in the United States and our global Phase 3 trial for ocular melanoma liver metatases. 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 CHEMOSAT/Melphalan/HDS, 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 CHEMOSAT/Melphalan/HDS, our ability to develop and commercialize the system would be impaired.

We manufacture CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS to purchasers.

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

We do not have written contracts with all our suppliers for the manufacture of components for CHEMOSAT/Melphalan/HDS. 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 CHEMOSAT/Melphalan/HDS in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS may be delayed.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing CHEMOSAT 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 CHEMOSAT 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 CHEMOSAT, 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.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing CHEMOSAT/Melphalan/HDS 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 CHEMOSAT 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 CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS 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 CHEMOSAT 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 satisfy foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;

- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

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

CHEMOSAT 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 CHEMOSAT 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, CHEMOSAT 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 CHEMOSAT 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 CHEMOSAT;
- our ability to obtain adequate reimbursement and convince healthcare payors that use of CHEMOSAT results in reduced treatment costs and improved outcomes for patients;
- whether CHEMOSAT 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 CHEMOSAT and our efforts to commercialize CHEMOSAT in the EEA may be unsuccessful.

Similar considerations apply in any other market where we receive approval. Successful commercialization of CHEMOSAT 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. CHEMOSAT/Melphalan/HDS 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 CHEMOSAT/Melphalan/HDS for other indications could affect our orphan drug exclusivity. In November 2008, the FDA granted us 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 us an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted us an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. The FDA granted us orphan drug designation of the drug melphalan for the treatment of HCC in October 2013 and for the treatment of ICC in July 2015. If CHEMOSAT/Melphalan/HDS 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. If another company has orphan drug designations for these same indications and receives marketing approval before we do, then we will be blocked from marketing approval for seven years from the date of their approval for the same indication of use.

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.

Risks Related to Intellectual Property

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

Our success depends significantly on our ability to maintain and protect our proprietary rights in the technologies and inventions used in or embodied by our product. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality, license and other contractual restrictions in our manufacturing, consulting, employment and other third party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We have not and may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product and technologies in any or all countries throughout the world could be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from copying our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased.

We do not have patent rights in certain foreign countries in which a market exists or may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Moreover, the United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a

patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

Our success depends in part on our ability to obtain patents, which can be an expensive, time consuming, and uncertain process, and the value of the patents is dependent in part on the breadth of coverage and the relationship between the coverage and the commercial product.

The patent position of medical drug and device companies is generally highly uncertain. The degree of patent protection we require may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us sufficient exclusivity, or to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file patent applications on the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or license from others in the future may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

- any patents we obtain or license from others in the future may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in the CHEMOSAT/Melphalan/HDS methods and/or devices that cause such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

Our success depends in part on our ability to commercialize CHEMOSAT/Melphalan/HDS prior to the expiration of our patent protection.

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, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our CHEMOSAT/Melphalan/HDS methods and devices, we may be open to competition from generic versions of such methods and devices.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, or to defend our products against assertion of intellectual property by a third party, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. 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.

In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, or may allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater

resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our product in one or more foreign countries.

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT/Melphalan/HDS could be found to infringe these patents. It is also possible that our competitors or potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

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.

Litigation related to infringement and other intellectual property claims such as trade secrets, with or without merit, is unpredictable, can be expensive and time-consuming, and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages, and attorneys' fees, and could prohibit us from using technologies essential to our product, any of which would have a material adverse effect on our business, results of operations, and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our product unless we can obtain licenses to use technology or ideas covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

If others have filed 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 or derivation proceedings declared by the USPTO to determine priority of invention, which could also be costly and could divert our attention from our business. If the USPTO declares an interference and determines that our patent or application is not entitled to a priority date earlier than that of the other patent application, our ability to maintain or obtain those patent rights will be curtailed. Similarly, if the USPTO declares a derivation proceeding and determines that the invention covered by our patent application was derived from another, we will not be able to obtain patent coverage of that invention.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT/Melphalan/HDS 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 United States patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

We maintain a patent license arrangement with a third party, and our future business may depend, in part, upon the maintenance of that arrangement.

Certain aspects of our next generation products may be covered by United States patents and United States patent applications owned by a third party and exclusively licensed to us. If we breach the terms of the license agreement, the license may be terminated by the licensor. If we do not meet certain commercialization obligations by 2019, the license may be converted to a non-exclusive license by the licensor. We cannot guarantee that the license will not be terminated or converted in the future. Without the patent license we will not be able to prevent others from practicing the technology covered by the licensed patent. Moreover, without the patent license, we may be subject to allegations of patent infringement by the patent owner. We cannot guarantee that the third party will fulfill its responsibilities under the license arrangement.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product and our technologies.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the United States patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other

requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. As case law continues to develop in response to this legislation, it is not yet clear what the full impact of the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

Our trademarks may be infringed or successfully challenged, resulting in harm to our business.

We rely on our trademarks as one means to distinguish our product from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

We may rely primarily on trade secret protection for important proprietary technologies in the European Economic Area.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Specifically in the European Economic Area (EEA), we rely on design patent and trade secret protection for CHEMOSAT/Melphalan/HDS. Without utility patent protection in the EEA covering the current version of CHEMOSAT/Melphalan/HDS, CHEMOSAT/Melphalan/HDS will only be covered by design patent and 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. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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 any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to CHEMOSAT/Melphalan/HDS will significantly impair our ability to commercialize CHEMOSAT 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 other foreign countries not mentioned above in the Intellectual Property and Other Rights section where we receive approval. Since we do not have issued patents for the current version of CHEMOSAT/Melphalan/HDS in these

countries, our ability to successfully commercialize CHEMOSAT/Melphalan/HDS will depend on our ability to maintain trade secret protection in these markets.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

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 CHEMOSAT/Melphalan/HDS. In addition, because CHEMOSAT/Melphalan/HDS 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 prospects. 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, and 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.

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.

The warrants issued in our February 2015, July 2015 and October 2016 offerings are subject to an exercise price adjustment upon certain equity issuances below $0.14 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 (the "Minimum Bid Price Requirement"), (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 (the "Minimum Stockholders' Equity Requirement").

On February 13, 2017 we were notified by the NASDAQ Listing Qualifications Department that we do not comply with the $1.00 minimum bid price 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, which ends on August 14, 2017. To regain compliance, our common stock is required to close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. It is our intention to meet the Minimum Bid Price Requirement during the 180-calendar day grace period, including by carrying out a reverse stock split, if necessary. If we seek to implement a reverse stock split in order to remain listed on NASDAQ, the announcement and/or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Failure of our stockholders to approve a proposed reverse stock split, or any delay in receiving stockholder approval of a proposed reverse stock split, may hinder our ability to regain compliance with the Minimum Bid Price Requirement.

As of December 31, 2016, our stockholders equity was below the Minimum Stockholders' Equity Requirement. We are currently evaluating potential solutions to regain compliance with the Minimum Stockholders' Equity Requirement. The Minimum Stockholders' Equity Requirement is not subject to an automatic grace period. There can be no assurance that we will meet the Minimum Stockholders' Equity Requirement or the Minimum Bid Price Requirement during any compliance period or in the future, or otherwise meet Nasdaq compliance standards, or that Nasdaq will grant the Company any relief from delisting as necessary, or that we will be able to ultimately meet applicable Nasdaq requirements for any such relief.

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.

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.

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 CHEMOSAT/Melphalan/HDS;
- 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.

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, 2016, we had an aggregate of 488.6 million shares of common stock authorized but not issued or outstanding, including 7.2 million shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $5.20. Subject to certain volume limitations imposed by The NASDAQ Capital Market in certain circumstances, we may issue all of these shares 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 warrants or 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.

Risks relating to the Note Financing

Our indebtedness reduces our financial flexibility and could impede our ability to operate.

On June 13, 2016 we issued an aggregate $35 million principal amount of senior secured convertible notes (the "notes"). The notes are payable in fourteen equal installments beginning in January 2017. Although the notes are payable

through the issuance of shares of our common stock to the noteholders, our ability to issue stock, instead of paying cash, to satisfy our payment obligations under the notes, is limited and subject to various conditions (including trading volume and stock price conditions for these notes) that we may not be able to meet. If we cannot meet these conditions, we could be required to repay some or all of the amounts due under the notes in cash, and we may not have the funds available to make one or more of such payments when due. Even if we do have funds so available, the use of cash to make such payments could adversely affect our ability to fund operations due to the diversion of necessary cash flow to fund operations to utilization for note payments. Furthermore, the notes impose certain restrictive covenants on us which may impede our ability to operate our business or raise further funds in the capital markets. For example, there are restrictions on incurring additional indebtedness, with exceptions, while the notes are outstanding.

Such payments are based upon a formula which uses as a conversion price a discount to market formula with a floor price of $0.05, thus the amount of shares issued can be significantly dilutive to our stockholders.

As part of the note financing, we are required to repay the principal on the notes in fourteen equal installments in cash or shares of common stock and we are required to issue shares upon the exercise of the Series C Warrants. The issuance of shares of our common stock pursuant to the notes and related Series C Warrants will result in significant dilution to our stockholders.

The notes will be repayable in cash or shares of common stock, at our election, subject to satisfaction of certain conditions. As of the date of this quarterly report, we do not believe that we will have the financial ability, nor would it be in the best interests of our stockholders, to make all payments on the notes in cash when due. Thus, we intend, as of the date hereof, to make such payments in shares of our common stock, to the greatest extent possible. The price at which we will be required to make any installment payments in shares of common stock is equal to the lowest of (i) the then prevailing conversion price, and (ii) initially 85% of the arithmetic average of the lower of (x) the three lowest daily weighted average prices of the common stock during the twenty (20) consecutive trading day period ending on the trading day immediately preceding the installment date and (y) the volume weighted average price of the common stock on the trading day immediately preceding the installment date; provided, that the amount determined in this clause (ii) shall in no event be less than $0.05.

At any time after the issuance of the notes, the notes will be convertible at the election of the holder into shares of common stock at a conversion price of $4.39 subject to adjustment as provided in the notes. Conversion of the notes is subject to a blocker provision which prevents any holder from converting into shares of common stock if its beneficial ownership of the common stock would exceed 4.99% (subject to adjustment not to exceed 9.99%) of our issued and outstanding common stock.

Further, we issued Series C Warrants exercisable to acquire 6,778,619 shares of common stock, which number is equal to 85% of the number of shares of common stock into which the notes were initially convertible. On December 31, 2017, the number of shares issuable upon exercise of the Series C Warrants will be increased by such number of shares equal to 75% of the difference of (i) the quotient of (x) the product of (A) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (B) the number of shares issued upon the conversion or exercise of any note or Series C Warrant (“Warrant Shares”) as of the date of issuance (as adjusted for certain events), divided by (y) the volume-weighted average price of the common stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events). Although we have the option to settle the principal payments on the notes in cash and certain conversion and exercise restrictions are placed upon the holders of the notes and Series C Warrants, the issuance of material amounts of common stock by us would cause our stockholders to experience significant dilution in their investment in our Company.

Our obligations to the holders of our notes are secured by a security interest in substantially all of our assets, so if we default on those obligations, the note holders could foreclose on our assets.

Our obligations under the notes and the transaction documents relating to the notes are secured by a first priority security interest in substantially all of our assets. As a result, if we default under our obligations under the notes or the transaction documents, the holders of the notes, acting through their appointed agent, could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

The holders of the notes have certain additional rights upon an event of default under the notes which could harm our business, financial condition and results of operations and could require us to reduce or cease operations.

Under the notes, the holders have certain rights upon an event of default. Such rights include (i) the remaining principal amount of the notes bearing interest at a rate of 15% per annum, (ii) receipt of payment in cash of an amount equal to (x) the remaining principal amount of the notes, accrued and unpaid interest and accrued and unpaid Late Charges (as defined in the notes) on such principal and interest, multiplied by (y) the redemption premium, equal to 118%, in addition to any and all other amounts due thereunder and (iii) the holder having the right to demand redemption of all or a portion of the notes, as described below. At any time after certain notice requirements for an event of default are triggered, a holder of notes may require us to redeem all or any portion of the note by delivering written notice. Each portion of the note subject to redemption would be redeemed by us in cash by wire transfer of immediately available funds at a price equal to the greater of (x) 118% of the principal amount being redeemed or (y) the product of (A) the conversion rate then in effect multiplied by (B) 118% of the volume weighted average price of the common stock on any trading day during the period commencing on the date immediately preceding such event of default and ending on the date such redemption payment is made. We may not have sufficient funds to settle the redemption price and, as described above, this could trigger rights under the security interest granted to the holders and result in the foreclosure of their security interests and liquidation of some or all of our assets.

The exercise of any of these rights upon an event of default could substantially harm our financial condition and force us to reduce or cease operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices currently occupy 6,877 square feet of office space at 1633 Broadway, Suite 22C, New York, New York under a sub-lease agreement that expires in March 2019. The Company leases two additional spaces in the United States including approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York and 17,320 square feet of office space at 810 Seventh Avenue, New York, New York. The lease agreements expire in October 2018 and March 2021 respectively. The Company has subleased the office space at 810 Seventh Avenue to unaffiliated third-parties. See Note 12 to the Company's audited financial statements contained in this Annual Report on Form 10-K for more details. Delcath owns a building containing approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, NY. These facilities house manufacturing, quality assurance and quality control, research and development, and office space. The Company also owns approximately four acres of land at 12 and 14 Park Road in Queensbury, New York. In addition, the Company leases a facility for office and manufacturing containing approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires August 2, 2021. The Company has sublet 5,662 square feet of this facility to an unaffiliated third-party. The Company believes substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

None.

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

	2016	
	High	Low
Quarter ended March 31, 2016	$8.64	$4.00
Quarter ended June 30, 2016	5.70	3.68
Quarter ended September 30, 2016	4.61	2.48
Quarter ended December 31, 2016	2.74	0.90

	2015	
	High	Low
Quarter ended March 31, 2015	$15.36	$24.93
Quarter ended June 30, 2015	12.96	23.04
Quarter ended September 30, 2015	6.38	14.72
Quarter ended December 31, 2015	6.24	9.96

On March 28, 2017 there were 34 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

All unregistered sales of equity securities during the period covered by this annual report on Form 10-K were previously disclosed in our current reports on Form 8-K.

Repurchases of Equity Securities

None.

Item 6. Selected Financial Data.

Omitted pursuant to Item 301(c) of Regulation S-K.

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

Overview

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational 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 systemic exposure and associated side effects. In Europe, our system is in commercial development under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT®), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our primary research focus is on ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of: The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, a Global Phase 3 clinical trial that is investigating overall survival in mOM, and a Global Phase 2 clinical trial program investigating Melphalan/HDS with and without sorafenib in HCC and Melphalan/HDS in ICC. The Company recently announced a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of a pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma. Our CDP also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC).

The direction and focus of our CDP for CHEMOSAT/Melphalan/HDS is informed by prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and United States regulatory activity has led to the implementation of several safety improvements to our product and the associated medical procedure.

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, HCC and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union where the prospect of securing adequate reimbursement for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT/Melphalan/HDS represents a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver. We believe that CHEMOSAT/Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Our Ability to Continue as a Going Concern

Our independent registered public accounting firm has issued its report dated March 28, 2017 in connection with the audit of our financial statements as of December 31, 2016 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, our notes contained in this Annual Report on Form 10-K for the year ended December 31, 2016 include a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on

acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our financial statements as of December 31, 2016 have been prepared under the assumption that we will continue as a going concern. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 clinical trials and research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At December 31, 2016, the Company had cash and cash equivalents totaling $4.4 million, as compared to cash and cash equivalents totaling $12.6 million at December 31, 2015. In addition, the Company has $27.3 million in restricted cash primarily related to the Notes discussed further in Note 9 of the Company's consolidated financial statements contained in this Annual Report on Form 10-K. During the year ended December 31, 2016, the Company used $14.2 million of cash for its operating activities, which compares to $16.4 million used for operating activities during the year ended December 31, 2015. The decrease of $2.2 million is primarily driven

by a reduction in restructuring expenses as well as continued efforts to improve efficiency in the Company's organization and operations. The Company believes it has sufficient capital to fund its operating activities through the first quarter of 2018.

Our consolidated financial statements as of December 31, 2016 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to Ocular Melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, 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 its 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 timing, scope, 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, and public offerings in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, and 2016, including registered direct offerings in 2007, 2009 and 2013, "at the market" equity offering programs in 2012 and 2013, and by a private placement of convertible notes in 2016. For a detailed discussion of the Company's various sales of securities see Note 10 to the Company's audited financial statements contained in this Annual Report on Form 10-K.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $77.4 million 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. Pursuant to SEC regulations, so long as the Company's public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

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

On July 19, 2016, shareholders of the Company approved, through a shareholder vote, an amendment to the Company's Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath's common stock at a ratio within a range of one-for-ten (1:10) to one-for-twenty (1:20). The reverse stock split became effective on July 21, 2016 at which time Delcath's common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen (1:16) split-adjusted basis. All owners of record as of the open of the NASDAQ market on July 21, 2016 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-sixteen exchange were rounded up to the next whole share. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company's consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying notes, have been restated to give retrospective presentation for the reverse stock split.

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, 2016:

	Payments Due by Period				
(in millions)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Activities:					
Future minimum lease payments, net of receipts due under subleases	$3.1	$1.0	$1.9	$0.2	$ —

Our operating lease obligations at December 31, 2016 include: the annual rent for our office space at 1633 Broadway, New York, New York, which will expire in March 2019; the annual rent under the lease for our office space at 810 Seventh Avenue, New York, New York, which will expire in March 2021 and of which a certain amount of expense has been offset by two sub-leases; the annual rent under the lease for a facility in Queensbury, New York, which will expire in October 2018; and the annual rent for our facility in

Galway, Ireland, which will expire in August 2021 and of which a certain amount of expense has been offset by a sub-lease. See Part I, Item 2, “Properties” and Notes 8 and 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 quarter of 2018 and anticipates that additional working capital will 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, 2016; Comparisons of Results of the Year Ended December 31, 2015

Revenue

The Company recorded approximately $2.0 million in total revenue during the year ended December 31, 2016. During the same period in 2015, Delcath recorded $1.7 million in total revenue related to product sales. The year over year increase is a result of greater product sales in 2016 as Delcath continues to see increased market acceptance of its product in the EU.

Cost of Goods Sold

During the year ended December 31, 2016, the Company recognized cost of goods sold of approximately $0.6 million related to product revenue of $2.0 million.

During the year ended December 31, 2015, the Company recognized cost of goods sold of approximately $0.5 million related to product revenue of $1.7 million.

The Company continues to expect 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: adjustments to volume forecasts; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and an improvement in efficiencies as the Company increases its production of CHEMOSAT.

Selling, General and Administrative Expenses

For the year ended December 31, 2016, selling, general and administrative expenses decreased to $9.4 million from $10.0 million for the year ended December 31, 2015. The decrease of $0.5 million is primarily attributable to a reduction in corporate expenses and depreciation.

Research and Development Expenses

For the year ended December 31, 2016, research and development expenses increased to $8.4 million from $6.5 million for the year ended December 31, 2015. The increase of $2.1 million is primarily due to the initiation of our Phase 3 trial during 2016 which is discussed in further detail in the Current Clinical Development Program section above.

Derivative Instrument Income

For the year ended December 31, 2016, derivative instrument income increase to $12.8 million from $0.6 million for the year ended December 31, 2015. The increase of $12.2 million is due to the issuance of warrants in 2016, as well as the mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 11 to the Company's audited financial statements contained in this Annual Report on Form 10-K.

Other Income/Expense and Interest Income/Expense

Other expense is primarily related to foreign currency exchange gains and losses.

Interest expense is related to:

1. the amortization of debt discounts discussed in Note 9 of the Company's consolidated financial statements contained in this Annual Report on Form 10-K; and

2. the restructuring lease liability discussed in Note 8 of the Company's consolidated financial statements contained in this Annual Report on Form 10-K.

Interest income is from a money market account and interest earned on operating accounts.

Net Loss

The Company had a net loss for the year ended December 31, 2016 of $18.0 million, an increase of $3.3 million, or 22.2%, compared to the net loss for the same period in 2015. This increase is primarily due to a $14.3 million increase in interest expense primarily related to the amortization of debt discounts further discussed in Note 9 of the Company's consolidated financial statements contained in this Annual Report on Form 10-K and a $1.4 million increase in operating expenses primarily related to increased investment in clinical trial initiatives. This was offset by a $12.2 million change in the fair value of the warrant liability, a non-cash item, and a $0.2 million improvement in gross profit due to increased sales.

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.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. A valuation allowance has been recorded against the Company's deferred tax assets as management believes it is more likely than not that the deferred tax assets will not be realized. In assessing whether it is more likely than not that the Company will realize the benefits of its deferred tax assets, management considers all forms of available evidence, including the Company's history of cumulative losses, estimates of future taxable income and losses (including reversals of deferred tax liabilities), and available tax planning strategies. Since the Company is in a cumulative loss position, it cannot rely on future taxable income as a source of taxable income because the Company views a cumulative loss position as significant objective negative evidence that would be difficult to overcome with the other subjective tests discussed. The Company does not have taxable income in prior years to absorb the carryback of net operating losses, nor has it implemented tax-planning strategies that would, if necessary, be implemented to allow for the usage of net operating losses.

On January 1, 2012, Delcath Systems, Inc. sold a portion of its intellectual property to Delcath Holdings Limited resulting in a taxable gain of $15.8 million in the U.S. based on the fair market value of the intangible that was transferred. The arms-length price, which was determined in accordance with Section 482, is a significant accounting estimate. The gain is deferred under U.S. GAAP principles until the asset is sold outside of the consolidated financial statements. The remaining deferred gain on the intercompany sale of intangible assets is $4.4 million and $6.7 million as of December 31, 2016 and December 31, 2015, respectively.

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 accelerated 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 Disclosures About Market Risk

The Company may be minimally 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 81,875 shares of its common stock and the issuance of warrants to purchase approximately 37,000 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 exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2016, the 2013 Warrants were exercisable at $112.64 per share with 36,848 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 153,750 shares of its common stock and the issuance of warrants to purchase 69,000 common shares (the "February 2015 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At December 31, 2016, the February 2015 Warrants were

exercisable at $1.61 per share with approximately 30,238 warrants outstanding. The February 2015 Warrants have a five-year term. There were approximately 40,000 February 2015 Warrants exercised during the year ended December 31, 2016 for proceeds of approximately $0.1 million.

In July 2015, the Company completed the sale of approximately 0.6 million Units consisting of 0.6 million shares of its common stock, Series A Warrants to purchase up to approximately 0.4 million common shares (“Series A Warrants”) and Series B Warrants to purchase Units consisting of up to approximately 0.6 million common shares (“Series B Warrants”) and 0.4 million Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the Series A and Series B Warrants. During the year ended December 31, 2016, approximately 0.1 million Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 0.4 million Series B Warrants expired on January 29, 2016 and the related liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 0.1 million Series A Warrants were issued. The exercise price of the Series A Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At December 31, 2016, the July 2015 Series A Warrants were exercisable at $1.61 with approximately 0.3 million warrants outstanding. The Series A Warrants have a five-year term. There were approximately 0.3 million July 2015 Series A Warrants exercised during the year ended December 31, 2016 for proceeds of $0.4 million.

In June 2016, the Company entered into a Securities Purchase Agreement pursuant to which the Company issued $35.0 million in principal face amount of senior secured convertible notes of the Company (the "Notes") and related Series C Warrants (the "Series C Warrants") to purchase 6.8 million additional shares of the Company's common stock. The Company allocated an estimated fair value of $27.8 million to the Series C Warrants. On December 29, 2017, the number of shares issuable upon exercise of the Series C Warrants (the "Warrant Shares") will be increased by such number of Warrant Shares equal to 75% of the difference of (i) the quotient of (A) the product of (x) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (y) the number of Warrant Shares as of the date of issuance (as adjusted for certain events), divided by (B) the volume-weighted average price of the Common Stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events). The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2016, The Series C Warrants were exercisable at $4.83 with approximately 6.8 million warrants outstanding. The Series C Warrants will be exercisable by the holder beginning on June 13, 2017 and continuing for a period of five years thereafter.

In October 2016, the Company completed the sale of 425,000 shares of its common stock and the issuance of warrants to purchase 148,750 common shares (the "October 2016 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At December 31, 2016, the October 2016 Warrants were exercisable at $1.61 per share with 78,750 warrants outstanding. The October 2016 Warrants have a five-year term. There were 70,000 October 2016 Warrants exercised during the year ended December 31, 2016 for proceeds of $0.1 million.

The proceeds allocated to the 2013 Warrants, February 2015 Warrants, the July 2015 Series A Warrants, the June 2016 Series C Warrants and the October 2016 Warrants (collectively, the "Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As a result, for the year ended December 31, 2016, the Company recorded pre-tax derivative instrument income of $12.8 million. The fair value of the Warrants totaled $18.8 million at December 31, 2016. Management expects that the Warrants outstanding at December 31, 2016 will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2016 was determined by using option pricing models assuming the following:

	October 2016 Warrants	June 2016 Series C Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	95.03%	94.19%	95.51%	95.52%	152.70%
Risk free interest rates	1.93%	2.01%	1.59%	1.47%	1.20%
Expected life (in years)	4.80	5.50	3.60	3.10	1.80

Item 8. Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Delcath Systems, Inc.

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc. and subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2016. 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and as of December 31, 2016 has an accumulated deficit of $279.2 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also discussed in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

New York, New York

March 28, 2017

DELCATH SYSTEMS, INC.

Consolidated Balance Sheets as of December 31, 2016 and 2015

(in thousands, except share and per share data)

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$4,409	$12,607
Restricted cash	27,287	—
Accounts receivables, net	403	277
Inventories	660	757
Prepaid expenses and other current assets	698	960
Deferred financing costs	699	—
Total current assets	34,156	14,601
Property, plant and equipment, net	1,083	1,132
Total assets	$35,239	$15,733
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$594	$284
Accrued expenses	3,407	2,243
Convertible notes payable, net of debt discount	13,343	—
Warrant liability	18,751	3,785
Total current liabilities	36,095	6,312
Deferred revenue	30	—
Other non-current liabilities	604	820
Total liabilities	36,729	7,132
Commitments and contingencies (Note 12)		
Stockholders' Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Common stock, $.01 par value; 500,000,000 shares authorized; 4,131,527 and 1,396,344 shares issued and 4,112,417 and 1,360,239 shares outstanding at December 31, 2016 and December 31, 2015, respectively*	41	14
Additional paid-in capital	277,749	269,863
Accumulated deficit	(279,188)	(261,217)

Treasury stock, at cost; 110 shares at December 31, 2016 and December 31, 2015, respectively*	(51)	(51)
Accumulated other comprehensive loss	(41)	(8)
Total stockholders' equity (deficit)	(1,490)	8,601
Total liabilities and stockholders' equity (deficit)	$35,239	$15,733

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Consolidated Statements of Operations and Comprehensive Loss

for the Years Ended December 31, 2016 and 2015

(in thousands, except share and per share data)

	Year ended December 31,	
	2016	2015
Product revenue	$1,992	$1,747
Cost of goods sold	(550)	(462)
Gross profit	1,442	1,285
Operating expenses:		
Selling, general and administrative expenses	9,434	10,009
Research and development costs	8,448	6,486
Total operating expenses	17,882	16,495
Operating loss	(16,440)	(15,210)
Derivative instrument income	12,780	564
Interest income	17	9
Other expense and interest expense	(14,328)	(67)
Net loss	$(17,971)	$(14,704)
Other comprehensive loss:		
Foreign currency translation adjustments	$(33)	$(28)
Comprehensive Loss	$(18,004)	$(14,732)
Common share data:		
Basic and diluted loss per share*	$(10.59)	$(14.56)
Weighted average number of basic and diluted shares outstanding*	1,696,237	1,010,105

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Consolidated Statements of Stockholders' Equity (Deficit)

for the Years Ended December 31, 2016 and 2015

(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 (Deficit)
Balance at December 31, 2014	608,775	$ 6	(110)	$ (51)	$ 264,683	$ (246,513)	$ 20	$ 18,145
Compensation expense for issuance of stock options	—	—	—	—	349	—	—	349
Compensation expense for issuance of restricted stock	35,991	—	—	—	308	—	—	308
Sale of common stock, net of expenses	738,125	8	—	—	8,471	—	—	8,479
Exercise of warrants	13,457	—	—	—	176	—	—	176
Fair value of warrants issued classified as liability	—	—	—	—	(4,247)	—	—	(4,247)
Fair value of warrants exercised	—	—	—	—	123	—	—	123
Net loss	—	—	—	—	—	(14,704)	—	(14,704)
Foreign currency translation	—	—	—	—	—	—	(28)	(28)
Balance at December 31, 2015	1,396,348	$ 14	(110)	$ (51)	$ 269,863	$ (261,217)	$ (8)	$ 8,601
Compensation expense for issuance of stock options	—	—	—	—	161	—	—	161
Compensation expense for	2,180	—	—	—	266	—	—	266

issuance of restricted stock								
Sale of common stock, net of expenses	428,067	4	—	—	1,007	—	—	1,011
Issuance of common stock for payments made in shares on convertible notes payable	1,805,299	18	—	—	631	—	—	649
Fair value of Beneficial conversion feature of convertible note	—	—	—	—	4,435	—	—	4,435
Fair value of warrants issued classified as liability	—	—	—	—	(707)	—	—	(707)
Exercise of warrants	499,633	5	—	—	1,367	—	—	1,372
Fair value of warrants exercised	—	—	—	—	726	—	—	726
Net loss	—	—	—	—	—	(17,971)	—	(17,971)
Foreign currency translation	—	—	—	—	—	—	(33)	(33)
Balance at December 31, 2016	4,131,527	$ 41	(110)	$ (51)	$ 277,749	$ (279,188)	$ (41)	$ (1,490)

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Consolidated Statements of Cash Flows

for the Years Ended December 31, 2016 and 2015

(in thousands)

	Year ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(17,971)	$(14,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	161	349
Restricted stock compensation expense	266	308
Depreciation expense	305	617
Loss on disposal of equipment	1	15
Warrant liability fair value adjustment	(12,780)	(564)
Non-cash interest income	(1)	(1)
Debt discount and deferred finance costs amortization	14,268	—
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	260	9
Increase in accounts receivable	(138)	(52)
(Increase) decrease in inventories	95	(420)
Increase (decrease) in accounts payable and accrued expenses	1,507	(1,757)
Increase in deferred revenue	30	—
Decrease in other non-current liabilities	(216)	(220)
Net cash used in operating activities	(14,213)	(16,420)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(258)	(170)
Increase in restricted cash	(1,087)	—
Proceeds from sales of property, plant and equipment	—	180
Net cash provided by (used in) investing activities	(1,345)	10
Cash flows from financing activities:		
Increase in restricted cash	(26,200)	—
Net proceeds from convertible debt financing	31,226	—
Net proceeds from sale of stock and exercise of warrants	2,383	8,655
Net cash provided by financing activities	7,409	8,655
Foreign currency effects on cash and cash equivalents	(49)	(107)
Net decrease in cash and cash equivalents	(8,198)	(7,862)
Cash and cash equivalents:		
Beginning of period	12,607	20,469
End of period	$4,409	$12,607

Supplemental non-cash activities:		
Conversion of convertible notes	$649	$-
Fair value of warrants issued	$28,472	$4,247
Fair value of warrants exercised	$726	$123

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(1) Description of Business

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational 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 systemic exposure and associated side effects. In Europe, our system is in commercial development under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT®), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our primary research focus is on ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Liquidity

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and has accumulated deficit of $279.2 million at December 31, 2016. As shown in the accompanying financial statements during the year ended December 31, 2016, the Company incurred net losses of $18.0 million and used $14.2 million of cash for its operating activities. These factors among others raise substantial doubt about the Company’s ability to continue as a going concern for a reasonable period of time.

The Company’s existence is dependent upon management’s ability to obtain additional funding sources or to enter into strategic alliances. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. There can be no assurance that the Company’s efforts will result in the resolution of the Company’s liquidity needs. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. The accompanying consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. On June 13, 2016 we issued an aggregate $35 million principal amount of senior secured convertible notes (the “Notes”). As a result, Management believes that its capital resources are adequate to fund operations through the first quarter of 2018, but anticipates that additional working capital will be required to continue operations. The Notes are payable in fourteen equal installments beginning in January 2017. Although the Notes are payable through the issuance of shares of our common stock to the noteholders, our ability to issue stock, instead of paying cash, to satisfy our payment obligations under the Notes, is limited and subject to various conditions (including trading volume and stock price conditions for these Notes) that we may not be able to meet. If we cannot meet these conditions, we could be required

to repay some or all of the amounts due under the Notes in cash, and we may not have the funds available to make one or more of such payments when due. 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.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(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 consolidated balance sheets and the amount of revenues and expenses reported for each of the 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.

Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded as restricted cash on the accompanying consolidated balance sheets. On June 13, 2016, the Company issued $35.0 million in senior secured convertible notes and received $32.2 million in cash proceeds. Under the terms of the notes, at closing, an initial tranche of $3.0 million was available for immediate use by the Company for general corporate purposes. The remaining cash proceeds of $29.2 million were available in a tranche of $3.0 million on December 29, 2016 ("First Release Date") and the remainder of $26.2 million will be available in four equal tranches to be released quarterly, beginning in February 2017 ("Subsequent Release Dates"), pursuant to an account control agreement whereby the restrictions on the proceeds are terminated when the Company meets certain equity conditions. The terms of the Notes are discussed in more detail in Note 9 contained in this Annual Report on Form 10-K. The cash is deposited in an account that is not FDIC insured.

Accounts Receivable

Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. Collections and payments from customers are monitored and a provision for estimated credit losses may be created based upon historical experience and specific customer collection issues that may be identified.

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, 2016 includes finished goods and components that have been purchased since April 2012. Therefore, 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 impacted 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.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

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, 2016 and 2015, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company adheres to 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.

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.

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.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

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. All such costs are charged to expense when incurred.

Research and Development

Research and development costs include the costs of materials used for clinical trials and R&D, 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. The Company classifies interest and penalty expense related to uncertain tax positions as a component of income tax expense. 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. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. See Note 13 for additional information.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

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 stock options, unvested restricted stock and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

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, 2016 and 2015 are as follows:

(in thousands, except share data)	2016	2015
Net loss – basic and diluted	$(17,971)	$(14,704)
Net loss per share – basic and diluted	(10.59)	(14.56)
Weighted average shares outstanding – basic and diluted	1,696,237	1,010,105

For the years ended December 31, 2016 and 2015, 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:

	2016	2015
Stock options	41,356	47,221
Unvested restricted shares	18,993	35,955
Warrants	7,216,020	1,128,688
Total	7,276,369	1,211,864

All share numbers presented in this footnote reflect a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016.

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of CHEMOSAT/Melphalan/HDS. A single management team that reports to the CEO and President 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.

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.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ("ASU 2014-09") that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for the Company beginning in its fiscal year 2018, and may be applied retrospectively to all prior periods presented or through a

cumulative adjustment to the opening retained earnings balance in the year of adoption. The Company intends to adopt this standard on January 1, 2018 and does not anticipate that this guidance will materially impact its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements — Going Concern, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (1) provides a definition of the term substantial doubt, (2) requires an evaluation every reporting period including interim periods, (3) provides principles for considering the mitigating effect of management's plans, (4) requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) requires an express statement and other disclosures when substantial doubt is not alleviated, and (6) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company has adopted this guidance.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 more closely aligns the measurement of inventory in U.S. GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company intends to adopt this standard on January 1, 2017 and does not anticipate that this guidance will materially impact its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740). ASU 2015-17 requires deferred tax liabilities and assets to be classified as non-current on the consolidated balance sheet. ASU 2015-17 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years and early application is permitted. ASU 2015-17 may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company intends to adopt this standard on January 1, 2017 and does not anticipate that this guidance will materially impact its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which requires entities to report a right-to-use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve months or less. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is currently evaluating the impact it may have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15,

2016, and early adoption is permitted. As of December 31, 2016, the Company has early adopted ASU 2016-09. The cumulative-effect adjustment to equity related to the recognition of excess tax benefits (offset by valuation allowance) is discussed in Note 13.

In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including interim periods within those fiscal years. An entity that elects early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The Company is currently evaluating the effects, if any, that the adoption of this guidance will have on the Company’s financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company intends to adopt this standard on January 1, 2018 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company’s financial statements.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(4) Inventories

Inventories consist of:

(in thousands)	December 31, 2016	December 31, 2015
Raw materials	$ 346	$ 360
Work-in-process	214	251
Finished goods	100	146
Total Inventory	$ 660	$ 757

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(in thousands)	December 31, 2016	December 31, 2015
Insurance premiums	$ 501	$ 625
Kits for clinical use	—	162
Other	197	173
Total prepaid expenses and other current assets	$ 698	$ 960

Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at December 31, 2016 and 2015.

(6) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)

	December 31, 2016	December 31, 2015
Buildings and land	$ 556	$ 556
Enterprise hardware and software	1,532	1,520
Leaseholds	1,504	1,305
Equipment	940	902
Furniture	354	355
Property, plant and equipment, gross	4,886	4,638
Accumulated depreciation	(3,803)	(3,506)
Property, plant and equipment, net	$ 1,083	$ 1,132

Depreciation expense for the years ended December 31, 2016 and 2015 was $0.3 million and $0.6 million, respectively.

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(7) Current Accrued Expenses

Current accrued expenses include the following:

(in thousands)	December 31, 2016	December 31, 2015
Clinical trial expenses	$ 1,365	$ 692
Compensation, excluding taxes	933	391
Professional fees	286	220
Short-term portion of lease restructuring	216	219
Other	607	721
Total accrued expenses	$ 3,407	$ 2,243

Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2016 and 2015.

(8) Restructuring Expenses

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, the Company entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement (“Sub-lease #1”) for approximately one-half of the office space at this location (“Suite 3500”), resulting in a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement (“Sub-lease #2”) for the remaining one-half of office space at its 810 Seventh Avenue office (“Suite 3505”), resulting in a lease restructuring reserve of approximately $0.7 million. As of December 31, 2016, the total remaining lease restructuring liability for its leased office space was approximately $0.8 million, of which approximately $0.2 million and $0.6 million were included in Accrued expenses and Other non-current liabilities on the consolidated balance sheets, respectively.

The following table provides the year-to-date activity of the Company’s restructuring reserves as of December 31, 2016:

(in thousands)	Lease Liability
Reserve balance at December 31, 2015	$ 1,039
Charges	—
Payments/Utilizations	(219)

Reserve balance at December 31, 2016 $ 820

(9) Convertible Notes Payable

On June 6, 2016, the Company entered into a Securities Purchase Agreement (the "SPA") with certain investors named on the Schedule of Buyers attached to the SPA pursuant to which the Company issued $35.0 million in principal face amount of senior secured convertible notes of the Company (the "Notes") and related Series C Warrants (the "Series C Warrants") to purchase additional shares of the Company's common stock, par value $0.01 per share ("Common Stock"). $35.0 million of the Notes were issued for cash proceeds of $32.2 million with an original issue discount in the amount of $2.8 million. The Notes are secured pursuant to a Security Agreement which creates a first priority security interest in all of the personal property (other than Excluded Collateral (as defined in the Security Agreement)) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future.

The Notes do not bear any ordinary interest. However, interest shall commence accruing immediately upon the occurrence of, and shall continue accruing during the continuance of, an Event of Default (as defined in the SPA), at 15% per annum and shall be computed on the basis of a 360-day year of twelve 30-day months and shall be payable, if applicable, in arrears for each calendar month on the first (1st) business day of each calendar month after any such interest accrues after an Event of Default.

Under the terms of the Notes, at closing the Company received an initial tranche of $3.0 million for immediate use for general corporate purposes. A second tranche of $3.0 million was released to the Company in December 2016. The remaining cash proceeds of $26.2 million are being held in a restricted account and will be released to the Company in subsequent tranches subject to certain equity conditions.

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As security for the Company's obligations under the Notes, $26.2 million of the total net cash proceeds is subject to a cash covenant restricting its use and requiring it to be held in a Master Restricted Account established in accordance with and pursuant to the terms and conditions of an account control agreement between the Company, the Buyers and Silicon Valley Bank (a "Controlled Account Agreement"). Subject to certain equity conditions, the $26.2 million of restricted cash will become unrestricted in equal quarterly installments during 2017, such that the balance will become unrestricted by the maturity date of the Notes, December 29, 2017, subject to satisfaction of certain equity conditions contained in the Notes.

In connection with the issuance of the Notes under the SPA, the Company also issued Series C Warrants, exercisable to acquire 6.8 million shares of Common Stock. On December 31, 2017, the number of Warrant Shares issuable upon exercise of the Series C Warrants will be increased by such number of Warrant Shares equal to 75% of the difference of (i) the quotient of (A) the product of (x) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (y) the number of Warrant Shares as of the date of issuance (as adjusted for certain events), divided by (B) the volume-weighted average price of the Common Stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events).

Each Series C Warrant will be exercisable by the holder beginning June 13, 2017 and continuing for a period of five years thereafter. The Series C Warrants are exercisable at $4.83 per share of common stock, subject to adjustments for certain dilutive events. The provisions in the Series C Warrants require the Company to account for the warrants as derivative liabilities. The Company recognized a discount to debt of $27.8 million related to the initial fair value of the Series C Warrants.

The Company has agreed to make amortization payments with respect to the Notes in fourteen (14) equal installments beginning seven (7) months after the original date of issuance of June 13, 2016 (each, an "Installment Date"). On each installment date, assuming certain equity conditions are met, the installment payment shall, at the election of the Company, automatically be converted into shares of Common Stock at a conversion rate defined in the agreement. If we cannot meet the equity conditions, we could be required to repay some or all of the amounts due under the notes in cash, and we may not have the funds available to make one or more of such payments when due. At any time after the issuance of the Notes, the Notes will be convertible at the election of the holder into shares of our Common Stock at a conversion price equal to $4.39, subject to adjustment as provided in the Notes.

As a result of the Notes including a feature such that the conversion price is based upon a formula which includes discounts to the market price of the common stock as well as having a lower effective conversion price considering the issuance discount and the value allocated to the Series C Warrants, the Company has recognized a beneficial conversion feature of $4.4 million. The original issue discount, the beneficial conversion feature, and the fair value of the issuance of the Series C Warrants are collectively considered the debt discount. The Company recorded a debt discount in the amount of $35.0 million which is being amortized over the life of the Notes using the effective interest method. As of December 31, 2016, $14.0 million of the debt discount has been amortized to interest expense. In addition to the debt discounts listed above, the Notes also include put options in the event of default and change in control as defined in the Notes. The value of such options was zero as the probability for such events was remote as of the issuance date and at December 31, 2016.

All debt issuance costs are accounted for as a deferred asset and will be amortized over the life of the Notes. As of December 31, 2016, the Company had incurred approximately $1.0 in debt issuance costs and had amortized approximately $0.3 million of those costs.

The following table summarizes the convertible notes outstanding at December 31, 2016:

(in thousands)	December 31, 2016
Convertible notes payable, principal	$ 34,351
Debt discounts	(21,008)
Net convertible note payable	$ 13,343

In 2016, the Company issued 1.8 million shares as payment for $0.6 million of convertible notes payable.

(10) Stockholders' Equity
Reverse Stock Split

On July 19, 2016, shareholders of the Company approved, through a shareholder vote, an amendment to the Company's Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath's common stock at a ratio within a range of one-for-ten (1:10) to one-for-twenty (1:20). The reverse stock split became effective on July 21, 2016 at which time Delcath's common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen

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(1:16) split-adjusted basis. All owners of record as of the open of the NASDAQ market on July 21, 2016 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-sixteen exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company's consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

In addition, shareholders of the Company also approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 170,000,000 to 500,000,000. The previously discussed reverse stock split had no impact on the increase in authorized shares.

Stock and Warrant Issuances

In October 2013, the Company completed the sale of 81,875 shares of its common stock and the issuance of warrants to purchase approximately 37,000 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 exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2016, the 2013 Warrants were exercisable at $112.64 per share with 36,848 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 153,750 shares of its common stock and the issuance of warrants to purchase 69,000 common shares (the "February 2015 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At December 31, 2016, the February 2015 Warrants were exercisable at $1.61 per share with approximately 30,238 warrants outstanding. The February 2015 Warrants have a five-year term. There were approximately 40,000 February 2015 Warrants exercised during the year ended December 31, 2016 for proceeds of approximately $0.1 million.

In July 2015, the Company completed the sale of approximately 0.6 million Units consisting of 0.6 million shares of its common stock, Series A Warrants to purchase up to approximately 0.4 million common shares ("Series A Warrants") and Series B Warrants to purchase Units consisting of up to approximately 0.6 million common shares ("Series B Warrants") and 0.4 million Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the Series A and Series B Warrants. During the year ended December 31, 2016, approximately 0.1 million Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 0.4 million Series B Warrants expired on January 29, 2016 and the related

liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 0.1 million Series A Warrants were issued. The exercise price of the Series A Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At December 31, 2016, the July 2015 Series A Warrants were exercisable at $1.61 with approximately 0.3 million warrants outstanding. The Series A Warrants have a five-year term. There were approximately 0.3 million July 2015 Series A Warrants exercised during the year ended December 31, 2016 for proceeds of $0.4 million.

In June 2016, the Company entered into a Securities Purchase Agreement pursuant to which the Company issued $35.0 million in principal face amount of the Notes and related Series C Warrants to purchase 6.8 million additional shares of the Company's common stock. The Company allocated an estimated fair value of $27.8 million to the Series C Warrants. On December 31, 2017, the number of Warrant Shares issuable upon exercise of the Series C Warrants will be increased by such number of Warrant Shares equal to 75% of the difference of (i) the quotient of (A) the product of (x) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (y) the number of Warrant Shares as of the date of issuance (as adjusted for certain events), divided by (B) the volume-weighted average price of the Common Stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events). The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At

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December 31, 2016, The Series C Warrants were exercisable at $4.83 with approximately 6.8 million warrants outstanding. The Series C Warrants will be exercisable by the holder beginning one year after the closing date and continuing for a period of five years thereafter.

In October 2016, the Company completed the sale of 425,000 shares of its common stock and the issuance of warrants to purchase 148,750 common shares (the "October 2016 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At December 31, 2016, the October 2016 Warrants were exercisable at $1.61 per share with 78,750 warrants outstanding. The October 2016 Warrants have a five-year term. There were 70,000 October 2016 Series C Warrants exercised during the year ended December 31, 2016 for proceeds of $0.1 million.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $77.4 million 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. Pursuant to SEC regulations, so long as the Company's public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 11,719 and 200,391 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In July 2016, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 106,250 shares, from 94,141 to 200,391 shares, upon a favorable vote by the Company's stockholders. 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, conditions, option price and the duration of each award. As of December 31, 2016, there were 120,883 shares available to grant under the 2009 Stock Incentive Plan.

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. Options and Restricted Stock granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee. Options granted under the Plans expire over varying terms, but not more than ten years from the date of grant.

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Stock option activity for 2016 and 2015 is as follows:

	Stock Option Activity under the Plans			Weighted Average
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Remaining Life (Years)
Outstanding at December 31, 2014	17,577	$19.84 - $3,921.92	$ 378.08	8.83
Granted	32,765	19.04	19.04	
Forfeited	(3,121)	19.04 - 2,713.60	480.16	
Outstanding at December 31, 2015	47,221	19.04-3,921.92	$ 122.40	8.95
Granted	—	—	—	
Forfeited	(5,865)	$19.04-$545.28	23.95	
Outstanding at December 31, 2016	41,356	$19.84-$3,788.80	$ 135.77	7.90
Exercisable at December 31, 2016	26,774	$19.04-$3,788.80	$ 199.31	7.63

For the years ended December 31, 2016 and 2015 the Company recognized compensation expense related to stock option grants of approximately $0.2 million and $0.3 million, respectively.

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 year ended December 31, 2015. There were no option grants during the year ended December 31, 2016:

	Year ended December 31, 2015	
Weighted average risk-free interest rates	1.82	%
Weighted average expected volatility	97.70	%
Dividend yield	—	
Weighted average expected option term (in years)	5.15	
Weighted average grant date fair value	$ 0.89	

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 2015, 2014, 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, 2016 and changes during the year ended December 31, 2016 and December 31, 2015 are presented below:

	Non-Vested Options	
	Number of Options	Weighted Average Exercise Price
Non-vested at January 1, 2015	14,116	$ 332.16
Granted	32,765	28.48
Vested	(9,994)	421.60
Forfeited	(1,416)	574.72
Non-vested at December 31, 2015	35,471	$ 22.55
Granted	—	—
Vested	(15,671)	26.85
Forfeited	(5,218)	19.23
Non-vested at December 31, 2016	14,582	$ 19.11

Additional compensation expense of approximately $55,000, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 1.06 years.

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2016 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 $0.92 as of December 31, 2016, 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, 2016 and changes during the year ended December 31, 2016 and December 31, 2015 are presented below:

	Restricted Stock Activity	
	Number of Shares	Weighted Average

		Grant Date Fair Value
Non-vested at January 1, 2015	1,857	$ 269.44
Granted	36,000	41.60
Vested	(1,854)	217.60
Forfeited	(8)	54.40
Non-vested at December 31, 2015	35,995	$ 19.04
Granted	4,687	4.32
Vested	(19,189)	15.44
Forfeited	(2,500)	19.04
Non-vested at December 31, 2016	18,993	$ 19.04

For the years ended December 31, 2016 and 2015 the Company recognized compensation expense related to restricted stock grants of approximately $0.3 million and $0.3 million, respectively. 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 1.12 years.

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Warrants

The Company issued warrants as part of its offerings in 2013, 2015, and 2016, as well as part of its issuance of convertible notes in 2016. A summary of warrant activity is as follows:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at January 1, 2014	53,134	28.00-112.64	$ 86.69	2.78
Issued	1,091,844		12.80	
Exercised	(13,457)		13.12	
Expired	(2,833)		13.12	
Outstanding at December 31, 2015	1,128,688	11.84-112.64	$ 16.02	2.16
Issued	7,031,929		4.80	
Exercised	(499,633)		2.75	
Expired	(444,964)		5.68	
Outstanding at December 31, 2016	7,216,020	1.61-112.64	$ 5.20	5.59

(11) Fair Value Measurements
Derivative Financial Instruments

As disclosed in Note 10 of the Company’s consolidated financial statements contained in this Annual Report on Form 10-K, the Company allocated part of the proceeds of public offerings in 2013, 2015 and 2016 of the Company’s common stock to warrants issued in connection with those transactions. In addition, the Company recognized a discount to debt related to the initial fair value of warrants issued in connection with the June 2016 Convertible Notes discussed in further detail in Note 9 of the Company’s consolidated financial statements contained in this Annual Report on Form 10-K. The valuations of the October 2013, February 2015, July 2015 Series A, June 2016 Series C, and October 2016 Warrants (collectively, the “Warrants”) were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the Warrants as a current liability due to certain provisions relating to price adjustments and potential cash payments, as well as the holders’ ability to exercise the warrants within twelve months of the reporting date and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period. Additionally, 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 models 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 risk-free 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 risk-free 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.

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For the year ended December 31, 2016, the Company recorded pre-tax derivative instrument income of $12.8 million. The resulting derivative instrument liabilities totaled $18.8 million at December 31, 2016. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2016 was determined by using option pricing models assuming the following:

	October 2016 Warrants	June 2016 Series C Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	95.03%	94.19%	95.51%	95.52%	152.70%
Risk free interest rates	1.93%	2.01%	1.59%	1.47%	1.20%
Expected life (in years)	4.80	5.50	3.60	3.10	1.80

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and 2015, 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

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2016	2015	2016	2015	2016	2015	2016	2015
Liabilities								
Derivative instrument liabilities	$—	—	$—	—	$18,751	$3,785	$18,751	$3,785

Fair Value Measurements Using Significant Unobservable

Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at January 1, 2015	$225
Total change in the liability included in earnings	(564)

Fair value of warrants issued	4,247
Fair value of warrants exercised	(123)
Balance at December 31, 2015	3,785
Total change in the liability included in earnings	(12,780)
Fair value of warrants issued	28,472
Fair value of warrants exercised	(726)
Balance at December 31, 2016	$18,751

(12) Commitments

Operating Leases

In February 2010, the Company entered into an agreement to lease (Initial Lease) 8,629 square feet of office space at 810 Seventh Avenue, New York, NY with an option to expand an additional 8,629 square feet. The term of the Initial Lease began in March, 2010. 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. 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 Initial Lease and the Lease Amendment provide for annual rent of $996,000 in 2015, $1.0 million in 2016, and $1.1 million in 2017-2020. As discussed in Note 8, the Company has sub-leased this office space.

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. 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, 2016 conversion rate): Year 1 – €106,051 ($115,458), Year 2 –

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€134,974 ($146,946), Year 3 – €159,077 ($173,187) and Years 4 and 5 – €183,179 ($199,427). Annual lease amounts in years 6 through 10 are to be paid at a fixed amount of €187,209 ($197,377). 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. The Company has sub-leased a portion of this facility.

In March 2016, the Company entered into a sub-lease agreement to lease approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term began in April 2016 and is effective through March 2019. The agreement provides for total annual base rent of $522,652.

In October 2016, 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 November 1, 2016 and was effective for a two year period. The agreement provides for total annual base rent of $48,223 and will expire October 2018.

Future minimum lease payments, net of receipts due under the terms of subleases, under all operating leases at December 31, 2016 are as follows:

(in thousands)	Future Lease Payment
2017	$ 952
2018	946
2019	529
2020	428
2021	254
2022	—
	$ 3,109

Rent expense totaled approximately $0.5 million and $0.4 million, for the years ended December 31, 2016 and 2015, respectively.

Letters of Credit

Under the terms of the lease agreement for office space at 810 Seventh Avenue, New York, NY, the Company is required to maintain a letter of credit in the amount of $881,297 which will expire in February 2017 if not renewed by the Company. Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, the Company is required to maintain a letter of credit in the amount of $130,663 which will expire with the sublease in March 2019.

(13) Income Taxes

There is no income tax provision for the years ended December 31, 2016 and 2015.

Income before income taxes consists of:

	Year Ended December 31,	
(in thousands)	2016	2015
Domestic	$(13,930)	$(11,276)
Foreign	(4,040)	(3,428)
Income before taxes	$(17,970)	$(14,704)

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

(in thousands)	Year Ended December 31, 2016	2015
Income taxes using U.S federal statutory rate	$(6,110)	$(4,999)
Loss of tax benefit of net operating loss carryforwards	68,795	—
Loss of tax benefit of state net operating loss carryforwards	13,891	—
Loss of tax benefit of tax credit carryforwards	4,023	—
Amortization of gain on IP migration	767	767
State income taxes, net of federal benefit	(2,576)	380
Foreign rate differential	1,141	920
Valuation allowance	(75,407)	2,649
Derivative charge	(4,345)	(192)
Stock option exercises and cancellations	53	674
Research and development costs	(250)	(199)
Other	18	—
	$—	$—

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

(in thousands)	December 31, 2016	December 31, 2015
Deferred tax assets:		
Employee compensation accruals	$ 1,386	$ 1,279
Accrued liabilities	343	633
Research tax credits	22	3,796
Other	55	66
Net operating losses	6,194	77,906
Total deferred tax assets	$ 8,000	$ 83,680
Deferred tax liabilities:		
Beneficial conversion feature	906	—
Total deferred tax liabilities	$ 906	$ —
Valuation allowance	7,094	83,680
Net deferred tax assets	$ —	$ —

As of December 31, 2016 and 2015, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $209.3 million and $184.5 million, respectively. A significant portion of the federal amount, $201.0 million, is subject to an annual limitation of approximately $72,500 as a result of a change in the Company's ownership in May 2003 and November 2016, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitations caused by the May 2003 and November 2016 ownership changes, approximately $205.7 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $3.6 million of net operating loss carryforwards remains available to offset future federal taxable income which will expire between 2018 and 2036. In addition, the Company's state net operating losses are also subject to annual limitations that generally follow the federal Section 382 provisions, adjusted for each state's respective income apportionment percentages. As of December 31, 2016 and 2015, the Company had net operating loss carryforwards for state and city income tax purposes between approximately $27.3 million and $153.0 million and between approximately $27.3 million and $109.7, respectively, which expire through 2036. As a result of the 382 limitations, approximately $150.2 million and $130.5 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $2.8 million and $2.7 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2016 and 2015, the Company had a net operating loss

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

carryforward for foreign income tax purposes of $21.1 million and $22.1 million, respectively, which have indefinite carryforward periods. As of December 31, 2016 and 2015, the Company had federal research and development tax credit carryforwards of approximately $4.0 million and $3.8 million, respectively, which expire through 2036. As a result of the section 382 limitation, the entire tax credit carryforward is expected to expire unutilized.

The Company has a tax benefit of approximately $1.0 million related to the exercise of non-qualified stock options. As a result of the adoption of ASU 2016-09, the $1.0 million tax benefit was recognized as a cumulative adjustment to retained earnings, offset by a $1 million valuation allowance against retained earnings.

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 decreased by approximately $76.6 million and increased by approximately $2.6 million in 2016 and 2015, respectively. The primary reason for the significant decrease in the valuation allowance during the current year is due to the reduction of recognizable deferred tax assets related net operating loss and credit carryforwards resulting from the Sec. 382 ownership change. The change in valuation allowance is as follows:

(in thousands)	December 31, 2016	December 31, 2015
Beginning balance	$ 83,680	$ 81,223
Charged to costs and expenses	(75,407)	2,649
Charged to additional paid-in capital	(1,854)	-
Charged to retained earnings	1,010	-
Charged to other comprehensive income	(335)	(192)
Ending balance	$ 7,094	$ 83,680

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 is currently under examination by the Internal Revenue Service for the period ending December 31, 2013. The examination commenced in the third quarter of 2015 and as of December 31, 2016, there have been no adjustments proposed. The Company has not recorded an uncertain tax position and therefore a table of unrecognized tax benefits has not been presented, and no interest or penalties have been accrued as of December 31, 2016. The Company's total amount of unrecognized tax benefits could increase within the next twelve months as a result of the exam. However, the effect of the outcome cannot be reasonably estimated as the IRS examination is ongoing. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by 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 is no longer subject to federal and state examination for tax years ending prior to December 31, 2013; tax years ending December 31, 2013 through December 31, 2016 remain open to examination. However, the Company’s tax years December 31, 1998 through December 31, 2016 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. 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.

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(14) Subsequent Events

NASDAQ Notification Letter

On February 13, 2017, the Company received a notification letter (the "Notice") from The NASDAQ Stock Market ("NASDAQ") advising the Company that for 30 consecutive trading days preceding the date of the Notice, the bid price of the Company's common stock had closed below the $1.00 per share minimum required for continued listing on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule"). The Notice stated that the Company will be provided 180 calendar days, or until August 14, 2017, to regain compliance with the Minimum Bid Price Rule. To do so, the bid price of the Company's common stock must close at or above $1.00 per share for a minimum of ten consecutive business days prior to that date. If, by August 14, 2017 the Company cannot demonstrate compliance with Marketplace Rule 5550(a)(2), then the NASDAQ staff will determine whether or not the Company meets The NASDAQ Capital Market initial listing criteria set forth in NASDAQ Marketplace Rule 5550, except for the bid price requirement. If the Company meets the initial listing criteria (with the exception of the bid price requirement) and provides written notice of its intention to cure the deficiency during an additional 180 calendar day compliance period, the NASDAQ staff will notify the Company that it has been granted such an additional compliance period (the "second compliance period"). If the Company is not eligible for the second compliance period, the NASDAQ staff will provide written notice that the Company's securities will be delisted. At that time, the Company may appeal the NASDAQ staff's determination to delist its securities to a Listing Qualifications Panel.

From January 1, 2017 through March 28, 2017, the Company issued 109,345,554 shares of Common Stock to the holders of the Notes as payment on the convertible notes payable.

From January 1, 2017 through March 28, 2017, the holders of Notes released an aggregate of approximately $6.6 million in cash previously funded to the Company and authorized the release of those funds from the restricted accounts of the Company in accordance with the Master Control Account Agreement.

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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 Chief Executive Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, Delcath's Chief Executive Officer concluded that the Company's disclosure controls and procedures as of December 31, 2016 (the end of the period covered by this Annual Report on Form 10-K), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in its reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer, 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, 2016 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, 2016. In making this assessment, it used the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2016, the Company's internal control over financial reporting was effective based on those criteria.

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 2017 Annual Meeting of Stockholders (the "Proxy Statement"). 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.

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 and is incorporated by reference herein. 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. Except as expressly stated herein, the information contained on our website does not constitute a part of this Annual Report on Form 10-K and is not incorporated by reference herein.

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accountant Fees and Services.

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

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules

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

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

Consolidated Balance Sheets at December 31, 2016 and 2015

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2016 and 2015

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016 and 2015

Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015

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.

Item 16. Form 10-K Summary.

None.

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/ Jennifer K. Simpson
Jennifer K. Simpson
President and Chief Executive Officer
(Principal Executive Officer)
Dated: March 28, 2017

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/ Jennifer K. Simpson Jennifer K. Simpson	President and Chief Executive Officer (Principal Executive Officer)	March 28, 2017
/s/ Barbra C. Keck Barbra C. Keck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2017
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	Chairman of the Board	March 28, 2017
/s/ Harold S. Koplewicz, M.D. Harold S. Koplewicz, M.D.	Director	March 28, 2017
/s/ William Rueckert William Rueckert	Director	March 28, 2017
/s/ Marco Taglietti Marco Taglietti	Director	March 28, 2017

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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Delcath Systems, Inc. (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed April 8, 2014 (Commission File No. 001-16133).
3.3	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)).
4.1	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 28, 2013 (Commission File No,.001-16133)).
4.2	Form of Warrant to Purchase Shares of Common Stock dated February 17, 2015 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 17, 2015 (Commission File No. 001-16133)).
4.3	Form of Series A Warrant to Purchase Shares of Common Stock dated July 21, 2015 (incorporated by reference to Exhibit 1.2 to the Company's Amendment No. 1 to Form S-1 filed July 7, 2015).
4.5	Form of Senior Secured Convertible Note (incorporated by reference to Exhibit A to the Securities Purchase Agreement included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 7, 2017 (Commission File No. 001-16133)).
4.6	Form of Series C Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit B to the Securities Purchase Agreement included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 7, 2017 (Commission File No. 001-16133)).
4.7	Form of Warrant to Purchase Shares of Common Stock dated October 5, 2016 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed October 4, 2016 (Commission File No. 001-16133)).
10.1	*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)).
10.2	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)).

10.3 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)).

10.4 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)).

10.5 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)).

10.6 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)).

10.7 †License, Supply and Contract Manufacturing Agreement between Synerx Pharma, LLC and Bioniche Teoranta and the Company dated as of October 13, 2010 (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010 (Commission File No. 001-16133)).

10.8 *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)).

10.9 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)).

Exhibit No.		Description
10.10		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)).
10.11	*	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)).
10.12		Form of Non-Statutory Stock Option Grant Letter (Non-Employee Directors) under the Company's 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed December 20, 2010 (Commission File No. 001-16133)).
10.13		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)).
10.14		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)).
10.15		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)).
10.16		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))
10.17		Sublease between Delcath Systems, Inc. and SLG 810 Seventh Lessee LLC, dated May 22, 2014. (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed May 28, 2014 (Commission File No. 001-16133))
10.18		Sublease Agreement between Delcath Systems, Inc. and ICV Partners, LLC dated August 18, 2014 (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed September 30, 2014 (Commission File No. 001-16133))
23.1	**	Consent of Grant Thornton LLP
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2	**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	**	XBRL Instance Document
101.SCH	**	XBRL Taxonomy Extension Schema Document
101.CAL	**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	**	XBRL Taxonomy Extension Presentation Linkbase Document

†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.