

**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, 2018  
 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)

**1633 Broadway, Suite 22C New York, NY**

(Address of principal executive offices)

**06-1245881**

(I.R.S. Employer  
Identification No.)

**10019**

(Zip Code)

**212-489-2100**

(Registrant's telephone number, including area code)

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

**Title of each class**

**Trading Symbol(s)**

**Name of each exchange on which registered**

Common stock

DCTH

OTCQB

**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 every Interactive Data File required to be submitted 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 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 or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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 OTC of \$2.78 per share, was \$2,591,399 as of June 30, 2018.

At June 14, 2019, the registrant had outstanding 18,277,807 shares of common stock, par value \$0.01 per share.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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## Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K for the period ended December 31, 2018 contains certain “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as “anticipates,” “expects,” “intends,” “plans,” “predicts,” “believes,” “seeks,” “estimates,” “could,” “would,” “will,” “may,” “can,” “continue,” “potential,” “should,” and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2018 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, 2018 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 and 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 and 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 and our internet address is [www.delcath.com](http://www.delcath.com).

### 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 the United States, Melphalan/HDS is considered a combination drug and device product, is referred to by its chemical name and delivery system, Melphalan/HDS, and is regulated as a drug by the Federal Food and Drug Administration (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 ocular melanoma liver metastases (“mOM”), hepatocellular carcinoma (“HCC”) and intrahepatic cholangiocarcinoma, a type of primary liver cancer (“ICC”). Melphalan/HDS has not been approved for sale in the United States.

In Europe, our delivery system, without the drug, is commercially available under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (marketed under the name CHEMOSAT and referred to herein as “CHEMOSAT”), where it has been used at major medical centers to treat a wide range of cancers of the liver. The current version of CHEMOSAT is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing CHEMOSAT in select markets in the European Union (the “EU”) where the prospect of securing reimbursement coverage 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. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

Our primary research focus is on mOM and ICC and certain other cancers that are metastatic to the liver. Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that Melphalan/HDS and CHEMOSAT represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies. 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 Melphalan/HDS is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the “FOCUS Trial”), a global registration clinical trial that is investigating objective response rate in mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the “ALIGN Trial”). Our product also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select Investigator Initiated Trials.

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

While we currently utilize third parties to manufacture some components of our product, we also have our own medical device manufacturing operations for certain components of our product and assemble, label and package our products in Queensbury, New York. See the discussion below under the caption “Manufacturing and Quality Assurance.” We commercialize our product in Europe through alliances with third parties.

### **Cancers in the Liver – A Significant Unmet Need**

Cancers of the liver remain a major unmet medical need globally. According to the American Cancer Society’s *Cancer Facts & Figures 2018* report, cancer is the second leading cause of death in the United States, with an estimated 609,640 deaths and 1.7 million new cases expected to be diagnosed in 2018. Cancer is one of the leading causes of death worldwide, accounting for approximately 9.6 million deaths and 18.1 million new cases in 2018 according to GLOBOCAN, the database of the International Association of Cancer Registries. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the United States in 2015 was \$80.2 billion. 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. Based on third party research that we commissioned in 2018, 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 for patients with ocular melanoma liver metastases. Based on the research conducted in 2018, 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.

### **Intrahepatic Cholangiocarcinoma**

Hepatobiliary cancers include HCC and ICC, and are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of hepatobiliary cancers are diagnosed in the United States and Europe annually. According to the American Cancer Society, approximately 42,030 new cases of these cancers are expected to be diagnosed in the United States in 2019, leading to approximately 31,780 deaths.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of hepatobiliary cases diagnosed in the United States and Europe annually. 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. According to third party research that we commissioned in 2018 we estimate that approximately 11,000 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.

According to the American Cancer Society, the overall five-year survival rate for hepatobiliary cancers in the United States is approximately 18%. For patients diagnosed with a localized stage of disease, the American Cancer Society estimates 5-year survival at 31%. The American Cancer Society estimates that 5-year survival for all cancers is 68%.

### **About CHEMOSAT and Melphalan/HDS**

Our product 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 a chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion, PHP<sup>®</sup>, (“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 and Melphalan/HDS is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included as part of the product offering, if approved. 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 CHEMOSAT and Melphalan/HDS Procedure**

As with many cancer therapies, treatment with CHEMOSAT and 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. Deaths due to certain adverse reactions within this integrated safety population were not observed to occur again during the clinical trials following the adoption of related protocol amendments.

## **Optimization of Procedure and Improvement of Medical Device Engineering of Key Components**

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 commercial treatment use in Europe, we have continued to develop and refine both CHEMOSAT and Melphalan/HDS and the PHP therapy. The 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 CHEMOSAT, which offered improved hemofiltration and other product enhancements.

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS, respectively, in a EU commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2017, 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.

## **Phase 3 - Melanoma Metastases Trial**

In February 2010, using an early version of our device and procedure, 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 therapy with melphalan using the Melphalan/HDS, or to a control group providing “best alternative care”. Patients assigned to the PHP therapy were eligible to receive up to six cycles of treatment at approximately four to six week intervals. Patients assigned to the “best alternative care” were permitted to cross-over into the PHP therapy at radiographic documentation of hepatic disease progression. A majority of the “best alternative care” patients did in fact cross over to the PHP therapy. The primary endpoint of the study was hepatic progression-free survival while 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 PHP therapy with melphalan (the “treatment group”) to “best alternative care” (the “control group”), showed that patients in the PHP therapy had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the “best alternative care” control group, according to the Independent Review Committee assessment. This reflects a 4-fold increase of hPFS over that of the “best alternative care” therapy, with 50% reduction in the risk of progression and/or death in the PHP therapy compared to the “best alternative care” therapy. Results of this study were published in the December 2015 issue of *Annals of Surgical Oncology*.

## **Phase 2 - Multi-Histology, Unresectable Hepatic Tumor Trial**

Also, in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP therapy 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 ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and overall survival in this limited number of patients exceeded that generally associated with this patient population.

### 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, and Cosmetic Act (FDCA) 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 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 treatment 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 clinical development program. Briefing materials presented to the 2013 ODAC panel by both the FDA and Delcath are available on our website at [www.delcath.com/clinical-bibliography](http://www.delcath.com/clinical-bibliography).

### 2013 Complete Response Letter

In September 2013, the FDA issued a complete response letter (CRL) relating to our NDA. The FDA issues a CRL after the review of an NDA has been completed and questions remain that preclude approval of the NDA in its current form. The deficiencies identified by FDA included, without limitation, 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 be addressed.

In January 2016, we announced the conclusion of a Special Protocol Assessment (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 represented an agreement with FDA that a specific Phase 3 trial would adequately address objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. The primary endpoint was overall survival, and secondary endpoints included progression-free survival, overall response rate and quality-of-life measures. However, on July 27, 2018, we announced an amendment to our Phase 3, randomized clinical trial in ocular melanoma liver metastases which, after much discussion regarding improvement of the enrollment rate with FDA, altered the trial protocol design to become a non-randomized, single-arm study with a different primary endpoint, thus invalidating the SPA agreement.

### Current Clinical Development Program

The focus of our current clinical development program is to generate clinical data for CHEMOSAT and 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 and Melphalan/HDS and to the PHP therapy have addressed the severe toxicity and procedure-related risks observed during the previous Phase 2 and 3 clinical trials. The clinical development program 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.

## **The FOCUS Trial – NCT02678572**

Our amended Phase 3 trial now entitled “A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma”, contemplates enrollment of a minimum of 80 patients with ocular melanoma metastatic to the liver. The rarity of ocular melanoma, absence of crossover to the experimental trial arm, and the availability of PHP® Therapy in a commercial setting in Europe all combined to inhibit enrollment in this trial under its previous protocol. Under the new protocol, the primary endpoint for the amended FOCUS trial will be objective response rate. Secondary endpoints will include duration of response, disease control rate, overall survival and progression-free survival. Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety and other pharmacokinetic measures. Inclusion and exclusion criteria remain unchanged. Patients previously enrolled in the Melphalan/HDS arm of the trial under the previous protocol will continue to be treated and evaluated as part of the amended trial. In addition, Delcath intends to provide to the FDA interpretable comparative survival data, even if the study is underpowered to demonstrate a statistically positive overall survival effect. We believe trial enrollment will complete in the second half of 2019 and will provide evidence to support an application for approval.

The Phase 3 clinical trial, as amended, invalidates the prior SPA agreement for the randomized version of the trial design. Full details of the registration Phase 3 clinical trial are available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

In December 2018, we announced that the independent Data Safety Monitoring Board (“DSMB”) for this trial completed its fourth review of safety data for treated patients in the trial under the prior protocol. The DSMB again recommended that the study continue without modification. The trial amendment does not change safety related procedures or invalidate prior DSMB evaluations.

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 lead investigator. In October 2018, we announced continued rollout of the amended protocol to participating centers in the United States and are working with approximately 30 leading cancer centers in the United States and Europe to participate in the trial.

Melphalan hydrochloride has been granted orphan drug status by the FDA for the 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 treatment experience in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL.

## **The ALIGN Trial- NCT03086993**

In April 2018, we announced the initiation of a new pivotal trial of Melphalan/HDS to treat patients with ICC titled “A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma” (the “ALIGN Trial”). The ALIGN Trial is being conducted under an SPA announced in March 2017. Under the terms of the SPA, the ALIGN Trial will enroll approximately 295 ICC patients at approximately 40 clinical sites in the United States and Europe. The primary endpoint is overall survival and secondary and exploratory endpoints include safety, progression-free survival, overall response rate and quality-of-life measures. The SPA agreement for the ALIGN Trial indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS in ICC. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

In October 2018, we announced the enrollment of the first patient in the ALIGN Trial at The University of Tennessee Health Science Center, Methodist University Hospital, and West Cancer Center in Memphis, Tennessee.



## 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 was intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. **This trial was terminated earlier than planned and is now closed to enrollment.**

*Protocol 202 NCT02415036* – Conducted in Europe, this trial was 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. **This trial was terminated earlier than planned and is now closed to enrollment.**

*ICC Cohort* – In 2015 we expanded *Protocol 202* to include a cohort of patients with ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. **This trial has completed enrollment and data from this study are being analyzed and will be disseminated publicly by the investigators.**

*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 at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP therapy does “demonstrate an efficacy signal in ICC and is worthy of full clinical investigation.” Data from this retrospective data collection provided important scientific support during our negotiations with the FDA for our SPA for the Pivotal ICC Trial. Data for the retrospective data collection were published in *European Radiology* in a paper entitled “Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival”. Details of the findings from this study are discussed below under “Recent Data Presentations”.

With the objectives of identifying an efficacy signal worthy of further clinical investigation now met, we have terminated enrollment in our Phase 2 program and have closed the Phase 2 trials in order to focus available resources on the FOCUS Trial and the ALIGN Trial.

Clinical trials are long in duration, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. 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 statements provided under Item 8 of this Annual Report on Form 10-K.

### European Investigator Initiated Trials

In addition to the clinical trials in our clinical development program, we are supporting data generation in other areas. We are currently conducting one Investigator Initiated Trial in colorectal carcinoma metastatic to the liver (“mCRC”) at Leiden University Medical Center in the Netherlands. We continue to evaluate other Investigatory Initiated Trials as suitable opportunities present themselves in Europe. We believe Investigatory Initiated Trials 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 Quality of Life 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 are non-randomized, and as such cannot be used for approval or promotional claims. However, we believe the patient registry will provide a valuable supportive data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

## Recent Data Presentations

In April 2019 we announced that results from a prospective Phase 2 study conducted by Leiden University Medical Center (“LUMC”) in the Netherlands on the use of CHEMOSAT to treat patients with metastatic ocular melanoma with liver metastases were presented at the European Conference on Interventional Oncology annual meeting.

The LUMC study entitled “Percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from ocular melanoma using the Delcath System’s second-generation hemofiltration system: a prospective phase II study” was conducted by a team led and presented by Dr. Mark Burgmans. The study evaluated 35 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between February 2014 and June 2017. The 35 patients underwent a total of 72 PHP therapy treatments, and tumor response was evaluable in 32 patients. Primary endpoints were overall response, overall survival, and progression free survival. Secondary measures included safety measures and hematologic toxicity.

Results of the study showed that one patient had a complete response and 22 had partial response, for a combined overall response rate of 74.1%. Overall survival was 20.3 months and mean progression free survival was 8.1 months.

Safety analysis showed a total of 14 serious adverse events were recorded. The hematologic toxicities were in a majority of the cases self-limiting and manageable. Investigators concluded that “PHP Therapy with the Generation Two version of CHEMOSAT is an effective and safe treatment for patients with hepatic metastases from ocular melanoma.”

The presentation at the European Conference, an Interventional Oncology updated data previously presented at the 2018 annual conference of the Cardiovascular and Interventional Radiological Society of Europe.

In October 2018, we announced that results of a multicenter retrospective analysis of outcomes in patients with ICC treated with CHEMOSAT were published in the journal *European Radiology*. The study is the first analysis on the use of Delcath’s PHP therapy for the treatment of ICC. The retrospective analysis, “Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival” was conducted by investigators in Germany, Italy, Netherlands, Spain and France with Dr. Steffen Marquardt of Hannover Medical School serving as lead author. The study evaluated 15 patients with ICC who were selected for PHP therapy after failing prior therapies. The patients were treated at nine hospitals throughout Europe between 2012 and 2016. Treatment outcomes were assessed by imaging every three months following PHP treatment.

After the first PHP therapy treatment, one patient (7%) had a complete response (“CR”), two patients (13%) had a partial response (“PR”), and stable disease (“SD”) was observed in eight patients (53%). This equates to a control rate (CR+PR+SD) of 73%. The complete response patient was not retreated and is still alive. Three patients (20%) progressed after the first treatment and one patient died prior to post-procedure imaging. Five of the patients with SD received a second PHP therapy treatment, resulting in one PR (20%), three SD (60%), and one PD (20%). During the follow-up phase, two of the SD patients received additional PHP therapy treatments. Median overall survival was 26.9 months from initial diagnosis and 7.6 months from first PHP treatment. One-year overall survival from first PHP was 40%. Median progression free survival (“PFS”) was 122 days, and median hepatic progression free survival (“hPFS”) was 131 days.

In their retrospective data collection, investigators stated that side-effects were potentially under-reported but were considered by the investigators to be tolerable and comparable to other systemic and local therapies. Nevertheless, in the context of the patient selection, baseline characteristics and number of PHP therapy treatments provided in this retrospective study, practitioners observed no adverse events of grades 3 or 4 severity during the PHP therapy treatment. Post-procedurally, significant hematological toxicity was observed in the form of anemia and thrombocytopenia 5-7 days after the PHP therapy treatment. Management with Granulocyte Colony Stimulating Factor was employed in some patients. These toxicities were considered consistent with those toxicities reported in the ABC 02 trial of systemic chemotherapy in this patient population. The ABC-02 trial was a randomized, controlled, phase 3 trial that was designed and developed by the ABC-02 Trial Management Group under the auspices of the Upper Gastrointestinal Cancer Clinical Studies Group of the United Kingdom National Cancer Research Institute. The study was conducted by investigators at 37 centers in the United Kingdom, and data were collected and analyzed at the Cancer Research United Kingdom and University College London Cancer Trials Centre, London. In this trial, patients were randomly assigned to receive cisplatin plus gemcitabine or gemcitabine alone for up to 24 weeks.

Investigators concluded that PHP therapy provides “promising response rates in patients with ICC,” and that side-effects were tolerable and comparable to other treatment strategies.

The study entitled “Survival and Response of Patients with Metastatic Ocular Melanoma after Chemosaturation Percutaneous Hepatic Perfusion” was conducted by M. Zeile, and A. Stang, et al of the Asklepios Barmbek Clinic in Hamburg, Germany. The study retrospectively evaluated response rates and overall survival in 12 patients with ocular melanoma liver metastases after treatment with Delcath’s PHP therapy. Five patients had metastases confined to the liver, and seven had additional extra-hepatic metastases. A total of 30 PHP therapy treatments were performed in the sample, and patients received an average of 2.5 treatments.

The objective response rate was 58.3%, and the disease control rate was 91.7% (1 complete response, 6 partial responses, 4 stable disease, and 1 progressive disease). Following the first PHP therapy treatment, progression free survival was 11.7 months and hPFS was 18.6 months. Median overall survival was 30.6 months following the treatment. Of the cohort of 12 patients, three patients were judged to be candidates for surgery following treatment with PHP therapy. Median overall survival among these patients was 76.8 months, though investigators cautioned that statistical conclusions cannot be drawn from the small sample size.

In May 2018, we announced that PHP therapy was featured in a Video Learning Session presented at the Annual Meeting of the European Conference of Interventional Oncology (“ECIO”). Dr. M.C. Burgmans of LUMC presented an overview of the PHP therapy, discussed the therapy’s developmental history, demonstrating how to perform the procedure, as well as outlining its potential in ocular melanoma liver metastases and intrahepatic cholangiocarcinoma, and highlighting ongoing clinical research. In his presentation, Dr. Burgmans stated his belief that PHP therapy should be considered as first line therapy in ocular melanoma liver metastases, an opinion informed by both our commercial experience in Europe and our prior research into this tumor type. LUMC is an experienced treatment center and has recently completed its 100<sup>th</sup> treatment using CHEMOSAT. We believe Dr. Burgmans’ comments reflect growing confidence in PHP therapy’s role in treating ocular melanoma liver metastases.

In January 2018, we announced the publication of a multi-center retrospective analysis of Delcath’s PHP therapy published in the peer-reviewed Journal of Surgical Oncology. The study entitled “Percutaneous Hepatic Perfusion with Melphalan in Uveal Melanoma: A Safe and Effective Treatment Modality in an Orphan Disease”, was conducted by researchers from Moffitt Cancer Center (Moffitt) in Tampa, Florida and the University Hospital Southampton (UHS) in the United Kingdom. The retrospective analysis of outcomes in 51 patients with liver metastases from ocular melanoma represents the largest data set compilation on the use of PHP therapy in this tumor type outside of a clinical trial setting.

Patients in the study were treated at the two centers between December 2008 and October 2016. Patients received up to four PHP therapy treatments at UHS and up to six PHP therapy treatments at Moffitt. All patients received at least one PHP therapy treatment, the median number of treatments per patient was two, and a total of 134 PHP therapy treatments were administered. Results showed that of the 51 treated patients, 22 (43.1%) showed a partial response, 3 (5.9%) showed a complete response, and 17 (33.3%) had stable disease. The six-month overall and hepatic disease control rates were 64.7% and 70.6% respectively. Survival analysis showed median overall survival of 15.3 months at the time of data cut off. One year overall survival was 64.6%.

Safety analysis showed that 19 patients (37.5%) had Grade 3 or 4 non-hematologic toxicity. Cardiovascular toxicity was seen in 17.6% of patients, a rate comparable to the company’s prior Phase 3 study. Further to implementation of the Gen 2 filter along with prophylactic use of growth factors, severe neutropenia was seen in 16 (31.3%) patients as opposed to 60 (85.7%) patients in the prior Phase 3 trial. Most significantly, as compared to the prior Phase 3 trial, there were no treatment related deaths. Researchers stated that PHP therapy “can be safely employed in appropriately selected ocular melanoma patients in institutions with appropriate expertise.”

The study authors further concluded that “results clearly demonstrate that PHP therapy appears to be an effective means of obtaining rapid intrahepatic disease control and is a sensible option in patients with predominant liver disease.” Researchers reported that their results support the use of PHP therapy in an integrated approach to the management of metastatic ocular melanoma and looked to the Company’s Phase 3 FOCUS Trial to further quantify the benefit and optimize treatment strategies for these patients.

## **Market Access and Commercial Clinical Adoption**

### **Europe**

Delcath’s marketing strategy in the European Economic Area (the “EEA”) includes establishing strategic alliances with partners that include license, supply, sales and marketing arrangements.

In December 2018, Delcath entered into a definitive licensing agreement (the “medac License”) for CHEMOSAT commercialization in Europe with medac Gesellschaft für klinische Spezialpräparate mbH (“medac”), a privately held, multi-national pharmaceutical company based in Wedel, Germany. Founded in 1970, medac specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases. medac has offices globally, worldwide partner agreements in over 90 countries, and approximately 1,200 employees.

Under the terms of the medac License, Delcath's European subsidiary, Delcath Systems, Ltd., exclusively licenses to medac the right to sell and market CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland, and the United Kingdom. The medac License provides for payment by medac to Delcath in a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties. We believe that medac is a well-suited partner to help advance CHEMOSAT commercialization in the European Union and neighboring countries. medac has offices throughout Europe, a well-established network among oncology key opinion leaders, and organizational scale necessary to help establish CHEMOSAT in the European treatment landscape for cancers of the liver.

Since launching CHEMOSAT in Europe, over 600 commercial treatments have been performed at over 25 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 cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine. Patients treated in Europe have received up to eight CHEMOSAT treatments, and the average number of repeat treatments performed on a per patient basis has consistently increased. In 2018, Leiden University Medical Centre in the Netherlands surpassed 100 treatments with CHEMOSAT since initiating procedures, the third European center to achieve the milestone.

In March 2018, we announced that we entered into a commercial supply agreement with Tillomed Laboratories, an EMCURE company, for the procurement of melphalan for use with CHEMOSAT in Europe. Tillomed Laboratories specializes in the licensing, marketing and supply of generic and branded pharmaceutical products to hospitals, wholesalers and pharmacists nationwide, in a cost-effective and timely manner. We believe this agreement establishes firm control over our melphalan supply chain in Europe, and over time will provide economies of scale. The supply agreement with Tillomed also gives Delcath access to the drug dossier for melphalan hydrochloride, an important asset that potentially provides a drug approval pathway with the European Medicines Agency ("EMA") in Europe. As many of the cancers of the liver we are treating with CHEMOSAT are orphan indications in the United States, a Marketing Authorization Application approval by the EMA for CHEMOSAT could potentially provide added market protection for these indications in Europe.

### **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, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In 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.

Effective with the execution of our license agreement with medac, medac will provide support for reimbursement applications in the European markets covered by our agreement.

### **Germany**

In October 2015, we announced that the Institut für das Entgeltsystem im Krankenhaus ("InEk"), the German federal reimbursement agency, established a national Zusatzentgelt ("ZE") reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group 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. Coverage levels under this process are negotiated between hospitals in Germany and regional sickness funds, with coverage levels renegotiated annually.

### **United Kingdom**

In May 2014, National Institute for Health and Care Clinical Excellence ("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 therapy 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.

Medac will continue consultations begun by Delcath with the Interventional Procedures Advisory Committee at NICE in England, providing recent clinical evidence with a view to moving existing Interventional Procedural Guidance from a research recommendation to specialist recommendation. This would enable greater scope for commercialization access to the therapy because it would allow more use by National Health Service (“NHS”) clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement within the NHS.

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.

## **Netherlands**

In the Netherlands CHEMOSAT has been performed at the Netherlands Cancer Institute in 2013 and at Leiden University Medical Centre since 2014. In June 2017, the Medical Oncology National Treatment Guidelines for Uveal Melanoma were updated and now include recommendations to consider CHEMOSAT in the treatment of liver metastases. We are hopeful that inclusion in the national guidelines and the support of clinicians treating patients with CHEMOSAT will eventually support an application for reimbursement in this market.

## **Spain**

In Spain, the Company has determined that there was no benefit to continuing with its relationship with a local sales agency. The Spanish market will now be served by medac.

## **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. In 2018, a second center has been activated in Turkey. We believe that these centers can serve as important location for CHEMOSAT treatment to patients in Turkey and throughout the region. The Company is represented in Turkey through a distribution partner.

## **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 FDCA, and its implementing regulations. Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and a 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 Investigational New Drug Application (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 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 an SPA. An 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 an 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.

## **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 recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA will deny approval of an NDA by issuing a Complete Response Letter (CRL) if the applicable statutory 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 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 4 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 FDCA: 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 FDCA 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. A 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 usually rendered in about 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. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug and prevents FDA from approving the same drug for the same condition during this period of exclusivity, except in certain circumstances such as where the subsequent applicant can demonstrate clinical superiority to the originally approved orphan drug. However, orphan drug exclusivity does not prevent FDA from approving the same drug for a different indication, or different drugs for the same indication.

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 recalls of products from the market, withdrawal of any potential approvals of a product, or civil or criminal penalties.

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 labeling. 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, CHEMOSAT 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 CHEMOSAT 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 version of CHEMOSAT, 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 EU 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. With the Delcath Systems Ltd. infrastructure now firmly in place, the Authorized Representative responsibilities have been formally transferred internally and there is no longer a need for a third party representative.

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 recently reviewed the Medical Device Directive legislative framework and promulgated Regulation (the “EU”) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (“EC”) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. This new Medical Device Regulation became effective on May 25, 2017, marking the start of a 3-year transition period for manufacturers selling medical device in Europe to comply with the new medical device regulation which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution and post marketing evaluation.

Effectively addressing these changes will require a complete review of our device operations to determine what is necessary to comply. We do not believe the medical device regulatory changes will impact our business at this time, though implementation of the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

### **Other International Regulations**

CHEMOSAT 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.

### **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 rights in six United States utility patents, one United States design patent, three pending United States utility patent applications, four issued foreign counterpart utility patents (including a European patent directed to our filter apparatus that has been validated in eight European countries and a European patent directed to our filter media apparatus), six issued foreign counterpart design patents, and two pending foreign counterpart patent applications. In October 2018 and February 2019 patents directed to our chemotherapy filtration system and a method of using our filter and frame apparatus were issued by the United States Patent and Trademark Office. A Notice of Allowance was obtained from the United States Patent and Trademark Office for the patent application entitled “Apparatus For Removing Chemotherapy Compounds from Blood” with allowed claims to a kit of parts capable of being assembled for delivering a small molecule chemotherapeutic agent to a subject. The allowed claims are directed to CHEMOSAT. A Hong Kong patent directed to our Filter and Frame Apparatus was issued in March of 2018. A European patent was granted for our chemotherapy filtration system in November 2018 and a European patent application directed to a method of using our filter and frame apparatus was granted in April 2019 by the European Patent Office.

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 CHEMOSAT and Melphalan/HDS that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as 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.

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.

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
7,022,097	Method For Treating Glandular Diseases and Malignancies	4/4/2006	Owned	6/24/2023
9,707,331	Apparatus For Removing Chemotherapy Compounds from Blood	7/18/2017	Owned	9/17/2034
10,098,997	Appartus For Removing Chemotherapy Compounds from Blood	10/16/2018	Owned	11/7/2032
D708749	Dual Filter	7/8/2014	Owned	7/8/2028
9,314,561	Filter and Frame Apparatus and Method of Use	4/19/2016	Owned	2/7/2034
10,195,334	Filter and Frame Apparatus and Method of Use	2/5/2019	Owned	1/16/2033
9,541,544	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	1/10/2017	Owned	8/28/2033
<i>Patent Applications in the United States</i>				
Application No.	Application Title	Filing Date	Owned or Licensed	
16/127,008	Apparatus For Removing Chemotherapy Compounds from Blood	9/10/2018	Owned	
16/231,486	Filter and Frame Apparatus and Method of Use	12/22/2018	Owned	
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/8/2016	Owned	

Foreign Patents				
Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
84.098	Dual Filter (Argentina)	6/29/2012	Owned	6/29/2027
343454	Dual Filter (Australia)	7/23/2012	Owned	6/25/2022
146201	Dual Filter (Canada)	5/15/2013	Owned	5/15/2023
ZL 201230277905.5	Dual Filter (China)	3/20/2013	Owned	6/22/2022
1333173	Dual Filter (Europe)	6/27/2012	Owned	6/25/2037
1456186	Dual Filter Cartridge for Fluid Filtration (Japan)	10/26/2012	Owned	10/26/2032
2797644	Filter and Frame Apparatus and Method of Use (Belgium)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (France)	4/12/2017	Owned	12/29/2032
602012031191.6	Filter and Frame Apparatus and Method of Use (Germany)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Great Britain)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Ireland)	4/12/2017	Owned	12/29/2032
502017000073120	Filter and Frame Apparatus and Method of Use (Italy)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Luxembourg)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Switzerland)	4/12/2017	Owned	12/29/2032
2776086	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/29/2018	Owned	11/7/2032
1203425	Filter and Frame Apparatus and Method of Use (Hong Kong)	3/23/2018	Owned	12/29/2032
3238762	Filter and Frame Apparatus and Method of Use (Europe)	4/17/2019	Owned	12/29/2032

#### Foreign Patent Applications

Application No.	Title	Filing Date	Owned or Licensed
17,176,952.400	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/7/2012	Owned
18164476.6	Filter and Frame Apparatus and Method of Use (Europe)	12/29/2012	Owned

## 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.

CHEMOSAT and Melphalan/HDS compete 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 ICC, gemcitabine plus cisplatin remains the standard of care for the treatment of ICC 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 dabrafenib) 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 of our product, including our proprietary filter media, and assemble and package CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and packaging/labeling/distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. We currently utilizes third-parties to manufacture some components of CHEMOSAT and Melphalan/HDS. CHEMOSAT and Melphalan/HDS and their 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. All Delcath facilities are presently ISO 13485:2016 certified.

### **Employees**

As of December 31, 2018, Delcath had 43 full-time employees. None of our employees are represented by a union and we believe our employee relationships are good.

**Risks Related to Our Business and Financial Condition**

*An investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this annual report, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock and the market value of our securities could decline, and you may lose all or part of your investment in our securities.*

***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 May XX, 2019 in connection with the audit of our financial statements as of December 31, 2018, 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, the notes to our financial statements for the year ended December 31, 2018 included in this Annual Report on Form 10-K contain 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 the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, Delcath would be forced to delay, reduce or eliminate its research and development programs or any commercialization efforts. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If the Company is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment.

***Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Delcath received a complete response letter from the FDA declining to approve our existing New Drug Application, or 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 response to our NDA, which the Company submitted to FDA in August 2012 seeking approval for use of our Melphalan/HDS Kit for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its current form and issued a complete response letter (CRL). A CRL is issued by the FDA when the review of an NDA is completed, and deficiencies remain that preclude approval of the NDA in its current form. The deficiencies in the CRL included, but were not limited to, a statement that Delcath must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of 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 required that the additional clinical trial(s) be conducted using the product the Company intends to market. Prior to conducting additional clinical trials, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information.

Delcath has initiated a pivotal Phase 3 trial in ocular melanoma metastases. Delcath had a SPA agreement with FDA for this study, which was initially designed as a randomized trial with a primary endpoint of overall survival. We subsequently amended the protocol so that the trial is a non-randomized, single-arm study with a primary endpoint of objective response rate. Although the changes to the protocol invalidated the SPA agreement, FDA stated that it would not object to Delcath conducting a study outside of a SPA agreement. However, Delcath will need to justify how the results of the study support a favorable risk-benefit assessment, particularly whether the response rate is sufficient to overcome the toxicity of Melphalan/HDS.

In addition, Delcath conducts and participates in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for Melphalan/HDS and HDS with other drug therapies. In 2014, Delcath initiated a Phase 2 clinical trial with Melphalan/HDS for hepatocellular carcinoma (“HCC”) in both the United States and Europe. In 2015, the Phase 2 clinical trial for HCC was expanded to include a cohort of patients with intrahepatic cholangiocarcinoma, a type of primary liver cancer (“ICC”). The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market’s perception of these clinical data or FDA’s perception of this clinical data, may adversely impact our ability to obtain approval, and our 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.

***The Company does not expect to generate significant revenue for the foreseeable future.***

Delcath’s entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT® and Melphalan/HDS and currently has only developed this system for the treatment of cancers in the liver. If CHEMOSAT and Melphalan/HDS for the treatment of cancers in the liver fail as commercial products, the Company has no other products to sell. In addition, since CHEMOSAT currently is approved for commercialization solely in the European Economic Area (the “EEA”) and limited other jurisdictions, if medac is unsuccessful in commercializing the product in the EEA and/or if Melphalan/HDS is not approved in the United States and elsewhere, the Company will have no means of generating revenue. In September 2013, the FDA issued a CRL with respect to the Company’s NDA for 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, Delcath does 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 the Company’s product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and 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, 2018, the Company had \$2.5 million in cash and cash equivalents. Delcath has had minimal revenue to date, and has a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2018 and 2017, the Company incurred net losses of approximately \$19.2 million and \$45.1 million, respectively and expects to continue to incur losses in 2019. Management believes its capital resources are adequate to fund operations through June 2019. To date, the Company has funded operations through a combination of private placements and public offerings of its securities, including convertible notes. If Delcath continues to incur losses, the Company may exhaust its capital resources, and as a result may be unable to complete its clinical trials, engage in product development and the regulatory approval process and commercialization of CHEMOSAT and Melphalan/HDS or any other versions of these products. If Delcath is unable to raise capital or generate sufficient revenue, it may not be able to pay its debts when they become due and may have to seek protection from the bankruptcy courts or enter into a receivership.

***If the Company cannot raise additional capital, its potential to generate future revenues will be significantly limited since it may not be able to further commercialize CHEMOSAT and Melphalan/HDS, complete its clinical trials or conduct future product development and clinical trials.***

The Company will require additional financing to complete its clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize its product in the EEA and any other markets where the Company may receive approval for its products. In addition, Delcath is 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, the Company could be subject to legal liability and its ability to complete product development projects or clinical trials could be impaired. The Company does not know if additional financing will be available when needed at all or on acceptable terms. If unable to obtain additional financing as needed, the Company may not be able to further commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete its development projects or clinical trials, which would result in a complete loss of an investment in our securities.

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

- clinical studies, including a Phase 3 clinical trial in ocular melanoma liver metastases and a registration trial in ICC;
- 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.

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 and Melphalan/HDS are 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 either civil or criminal administrative or judicially-imposed sanctions and/or other penalties.

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act 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 Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

The Company is not permitted to market Melphalan/HDS in the United States unless and until it obtains regulatory approval from the FDA. To market the product in the United States, Delcath 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 the Company could encounter problems that cause it 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 determine that the risk:benefit profile is not favorable;
- 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 the Company;
- 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.



Furthermore, 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.

Undesirable side effects caused by any product candidate that Delcath develops could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, the Company submitted the Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA declined to approve the NDA and issued a CRL. The deficiencies in the CRL included, but were not limited to, a statement that the Company 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, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information. However, even if the Company completes its clinical trials and satisfies all the requirements of the CRL, it 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 and Melphalan/HDS or any products that the Company develops in the future;
- impose additional costs on Delcath;
- diminish any competitive advantages that may be attained; and
- adversely affect the Company’s ability to generate revenues.

***Delcath has 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 the Company may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, Delcath’s 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. Delcath’s ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that the Company’s promotion of CHEMOSAT is found to be outside the scope of its approved indication, Delcath may be subject to fines or other regulatory action, limiting its ability to commercialize CHEMOSAT in the EEA.

The Company is 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, Delcath’s ability to commercialize CHEMOSAT in the EEA will be significantly limited. Delcath’s product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference Delcath’s 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 Delcath’s 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 CHEMOSAT 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 CHEMOSAT and/or to prescribe the use of melphalan independently, the Company’s sales opportunities in the EEA will be significantly impaired.

***While the Company has obtained the right to affix the CE Mark, it will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where it receives marketing authorization or approval.***

In April 2012, the Company obtained the required certification from its European Notified Body, enabling Delcath 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 version of CHEMOSAT. In order to maintain the right to affix the CE Mark in the EEA, the Company is 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, the Company is subject to ongoing audits by its European Notified Body, and the right to affix the CE Mark to the Generation Two version of CHEMOSAT may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that CHEMOSAT or Melphalan/HDS is approved by the FDA or any other regulatory agency, Delcath will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, the Company 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 current good manufacturing practice (“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 pre-clinical or clinical trials that the Company conducts post-approval. In addition, post-marketing requirements for CHEMOSAT and 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, restrictions on distribution or use 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 untitled 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 the Company is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on the business, results of operations, financial condition and prospects of the Company.

***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.***

The Company 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 agents or compounds used in our system. The Company is seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. Delcath must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with the system that Delcath intends 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 the Company uses in its 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. Delcath may encounter delays or rejections for various reasons, including its inability to enroll enough patients to complete the clinical trials. Moreover, approval policies or regulations may change. If the Company does not obtain and maintain regulatory approval for Melphalan/HDS and the use of melphalan or other chemotherapeutic agents, the value of the Company, results of operations and its ability to raise additional capital will be harmed.

In August 2012, Delcath submitted a NDA seeking an indication for ocular melanoma liver metastases for Melphalan/HDS. In September 2013, the FDA issued a CRL indicating that the Company 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. Our current Phase 3 trial in ocular melanoma liver metastases, the FOCUS Trial, is not randomized and uses a different primary efficacy outcome measure. Failure to obtain FDA approval will have a material adverse effect on Delcath's business, financial condition and results of operations.

***Even if the Company obtains regulatory approval for Melphalan/HDS in the United States, its ability to market 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 Melphalan/HDS, our ability to market and promote Melphalan/HDS would be limited to the approved indication, so even with FDA approval, 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, the Company may only market Melphalan/HDS, if approved by the FDA, for its approved indication and 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, Delcath may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the Company 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, the Company 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, the Company 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.

The Company has initiated an open-label Phase 3 clinical trial in ocular melanoma liver metastases called the FOCUS Trial. The Company has also initiated a Phase 3 registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), called the ALIGN trial, for which the Company has received agreement on a SPA from the FDA.

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;
- Delcath may encounter delays or rejections based on changes in regulatory agency policies during the period in which it is developing a system or the period required for review of any application for regulatory agency approval;
- enrollment in the Company's clinical trials may proceed more slowly than expected;
- the Company's 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 the Company's NDA submissions;

- the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay Delcath's 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 the Company to cease the development of Melphalan/HDS for other indications. If Delcath is unable to develop Melphalan/HDS for other indications, the future growth of our business could be negatively impacted. In addition, Delcath has limited clinical data relating to the effectiveness of Melphalan/HDS in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT and Melphalan/HDS and significantly reduce Delcath's ability to commercialize CHEMOSAT and Melphalan/HDS.

***The Company relies on third parties to conduct certain elements of the clinical trials for CHEMOSAT and Melphalan/HDS, and if they do not perform their obligations to Delcath, the Company may not be able to obtain regulatory approvals for its system.***

The Company designs the clinical trials for Melphalan/HDS, but relies on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. Delcath relies heavily on these parties for the execution of its clinical studies and control only certain aspects of their activities. Accordingly, the Company may have less control over the timing and other aspects of these clinical trials than if Delcath conducted them entirely on its own. The Company relies upon third parties to conduct monitoring and data collection of its ongoing and future clinical trials, including its Phase 3 ocular melanoma trial and pivotal ICC trial. Although Delcath relies on these third parties to manage the data from these clinical trials, Delcath is responsible for confirming that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require Delcath 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. The Company's reliance on third parties does not relieve it of these responsibilities and requirements and if Delcath or the third parties upon whom the Company relies for its clinical trials fail to comply with the applicable GCPs, the data generated in its clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require Delcath to perform additional trials before approving our marketing application. The Company cannot assure you that, upon inspection, the FDA will determine that any of its clinical trials comply or complied with GCPs. In addition, Delcath's clinical trials must be conducted with product that complies with the FDA's cGMP requirements. The Company's failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure 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, Delcath may not be able to successfully commercialize CHEMOSAT in the EEA.***

The Company has obtained the right to affix the CE Mark for CHEMOSAT, and under the medac License, medac intends to seek third-party or government reimbursement within those countries in the EEA where it expects to market and sell CHEMOSAT. In Germany, the Company had received a ZE diagnostic-related group code ("ZE Code"), which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where medac is able to obtain reimbursement, local policy could limit the Company's ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until medac obtains government reimbursement, it will rely on private payors or local pre-approved funds where available. There are also no assurances that third-party payors or government health agencies of Member States of the EEA will reimburse use of CHEMOSAT in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the 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.***

The Company's ability to commercialize CHEMOSAT under the medac License and Melphalan/HDS 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. Delcath 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 Delcath to establish and maintain price levels sufficient for the Company to realize an appropriate return on its 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 and Melphalan/HDS and the demand for CHEMOSAT and 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") was enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. The Trump administration has taken executive actions and members of Congress have recently introduced legislative proposals to significantly alter the ACA. It is uncertain if such executive actions will be upheld or legislative proposals will be enacted or what consequences these actions and legislative proposals or the implementation of existing provisions of ACA will have on our efforts to commercialize CHEMOSAT and Melphalan/HDS.

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

The commercial success of CHEMOSAT and Melphalan/HDS, if approved, will depend upon their acceptance by the medical community and third-party payors 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 and Melphalan/HDS or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, and CHEMOSAT and Melphalan/HDS as effective and desirable, our efforts to market CHEMOSAT and Melphalan/HDS may fail, which would cause us to cease operation.

***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. The Company expects 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 and 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 and/or 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 and/or Melphalan/HDS, thereby harming our results of operations.

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

There are three third-party manufacturers of melphalan in certain countries of the EEA of which the Company is aware. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, Delcath may be unable to successfully commercialize our product in the EEA.

Under the current 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, the Company is aware that there are currently three approved manufacturers of melphalan in certain countries of the EEA. As a result, there may not be sufficient supply of melphalan for use with CHEMOSAT, and any adverse change in a manufacturer's commercial operations or regulatory approval status may seriously impair Delcath's sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where Delcath may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, the Company will be unable to commercialize CHEMOSAT in these markets, thereby limiting future sales opportunities.

***If the Company cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents it will be unable to successfully commercialize Melphalan/HDS in the United States or complete its global Phase 3 trial in ocular melanoma liver metastases, registration trial in ICC, or any future clinical trials.***

The Company has 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 its branded melphalan for injection. The agreement with Synerx and Bioniche currently represents Delcath's sole source of branded melphalan in the United States. The Company intends to use the melphalan supplied by Synerx and Bioniche to conduct its global Phase 3 trials for ocular melanoma liver metastases and ICC. Delcath may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that it will use in the future for its clinical trial program and the commercialization of CHEMOSAT and Melphalan/HDS, as well as for labeling and finishing services. The Company may not be able to enter into such arrangements on acceptable terms or at all. Every manufacturer is subject to inspection by FDA and must meet all cGMP regulatory requirements. To manufacture melphalan or other chemotherapeutic agents on its own, Delcath 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 the Company chooses to manufacture for its system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on the Company's revenues and profitability. If Delcath is unable to obtain sufficient melphalan and labeling services on acceptable terms, if it should encounter delays or difficulties in its relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, Delcath's business, financial condition and results of operations may be materially harmed.

***If we cannot successfully manufacture CHEMOSAT and Melphalan/HDS, our ability to develop and commercialize the system would be impaired.***

We manufacture certain components of our products, including our proprietary filter media, and assemble and package CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and packaging/labeling/distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. We currently utilizes third-parties to manufacture some components of CHEMOSAT and Melphalan/HDS.

We have a limited manufacturing history and we may not be able to manufacture our products 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 our products from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver CHEMOSAT and Melphalan/HDS to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT and Melphalan/HDS may adversely affect our ability to obtain regulatory approval in the United States and 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 and 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.

The Company has implemented updated quality systems throughout our organization 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. All Delcath facilities are presently ISO 13485:2016 certified. If our Queensbury, NY fails to maintain compliance with ISO 13485 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 and Melphalan/HDS in our Galway, Ireland facility or elsewhere in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

***The Company does not have written contracts with all of its suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS.***

The Company does not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If Delcath is unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, it may not be able to manufacture CHEMOSAT and Melphalan/HDS in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and Melphalan/HDS in the United States, the EEA and elsewhere may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT and Melphalan/HDS are currently manufactured for Delcath in small quantities and may require significantly greater quantities to further commercialize the product. The Company may not be able to find alternate sources of comparable components. If Delcath is unable to obtain adequate supplies of components from existing suppliers or needs to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and Melphalan/HDS may be delayed.

***Even if the Company receives FDA or other foreign regulatory approvals, Delcath may be unsuccessful in commercializing CHEMOSAT and Melphalan/HDS in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.***

Outside the EEA, even if the Company obtains regulatory approval from the FDA or other foreign regulatory agencies, its ability to commercialize CHEMOSAT and Melphalan/HDS may be limited due to Delcath's inexperience in developing a sales, marketing and distribution infrastructure. If the Company is unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market its products in the United States or foreign countries, particularly in Asia, Delcath's efforts to commercialize CHEMOSAT and Melphalan/HDS or any other product outside of the EEA may be less successful.

Even if the Company is successful in commercializing CHEMOSAT and Melphalan/HDS in the EEA, Delcath may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so the Company's EEA marketing strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, Delcath's efforts to promote and market CHEMOSAT in each of its target markets may fail in any or all of those markets.

***The Company's plan to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and Melphalan/HDS may not be successful.***

The Company 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, Delcath may face competition in its search for alliances. As a result, the Company may not be able to enter into any additional alliances on acceptable terms, if at all. The Company's collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and Melphalan/HDS or any other product. The success of any collaboration will depend upon Delcath's ability to perform its obligations under any agreements as well as factors beyond its control, such as the commitment of its collaborators and the timely performance of their obligations. The terms of any such collaboration may permit Delcath's 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 the Company's expectations or its collaborators may breach their agreements with the Company. In addition, any third parties with which the Company collaborates may have significant control over important aspects of the development and commercialization of Delcath's products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. Delcath is not able to control or influence the amount and timing of resources that any collaborator may devote to the Company's research and development programs or the commercialization, marketing or distribution of its products. The Company 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 and Melphalan/HDS or the withdrawal of their support for its products. The failure of any such collaboration could have a material adverse effect on its business.

***If the Company fails to overcome the challenges inherent in international operations, its business and results of operations may be materially adversely affected.***

Currently the Company has only received authorization to market CHEMOSAT in the EEA, and intends to seek similar authorization or approvals in other foreign countries. As a result, Delcath expects international sales of its products to account for a significant portion of its revenue, which exposes Delcath to risks inherent in international operations. To accommodate the Company's international sales, Delcath will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of its customers. Accordingly, Delcath will face additional risks resulting from its 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 its 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 the Company establishes 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 its 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 the Company fails to overcome the challenges it encounters in its international operations, Delcath's business and results of operations may be materially adversely affected.

***Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect the Company's ability to achieve meaningful revenues or profit.***

Competition in the cancer treatment industry is intense. CHEMOSAT and Melphalan/HDS compete with all forms of liver cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of the Company's 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, Delcath's revenues or profitability will be substantially reduced.

Delcath has the following six orphan drug designations:

- the drug melphalan for the treatment of patients with cutaneous melanoma (November 2008)
- the drug melphalan for the treatment of patients with ocular melanoma (November 2008)
- the drug melphalan for the treatment of patients with neuroendocrine tumors (May 2009)
- the drug doxorubicin for the treatment of patients with primary liver cancer (August 2009)



- the drug melphalan for the treatment of HCC (October 2013)
- the drug melphalan or the treatment of ICC (July 2015)

If another company has orphan drug designations for the same drug and indication and receives marketing approval before Delcath does, then the Company will be blocked from marketing approval for seven years from the date of its approval for the same indication of use unless the Company can make a showing of the clinical superiority of its drug.

***The loss of key personnel could adversely affect the Company's business.***

Our success depends upon the efforts of our employees. The loss of any of the Company's senior executives or other key employees could harm its business. Competition for experienced personnel is intense and, if key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly identified and hired. The competition for qualified individuals exists in all functional areas, which makes it difficult to attract and retain the qualified employees we need to operate our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, technical, commercial and administrative personnel. If we are unable to attract new employees and retain our current key employees, Delcath's ability to compete could be adversely affected and the development and commercialization of our products could be delayed or negatively impacted.

***We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.***

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Any of these event may cause us to have difficulty preventing, detecting, and controlling fraud, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

***We are subject to certain data privacy and security requirements, which are complex and varied among jurisdictions. Any failure to ensure adherence to these requirements could subject us to fines and penalties, and damage our reputation.***

We are required to comply with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consume protection laws, which govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe the products we currently sell or may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 and comparable state laws. The legislative landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notifications. Any of these laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

**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 for our product and technologies 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 and technologies.

***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 CHEMOSAT and 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 and 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 and 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 rights 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 and 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 and Melphalan/HDS or any other Delcath 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.

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

Legislation introduced earlier this decade increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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-inventor-to-file" system. Under a "first-inventor-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-inventor-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 and Melphalan/HDS. Without utility patent protection in the EEA covering the current version of CHEMOSAT and Melphalan/HDS, CHEMOSAT and 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 and 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 of Item 1 hereof where we receive approval. Since we do not have issued patents for the current version of CHEMOSAT and Melphalan/HDS in these countries, our ability to successfully commercialize CHEMOSAT and 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**

***The Company may be the subject of product liability claims or product recalls, and it may be unable to maintain insurance adequate to cover potential liabilities.***

The Company's business exposes Delcath to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT and Melphalan/HDS. In addition, because CHEMOSAT and Melphalan/HDS are intended for use in patients with cancer, there is an increased risk of death among the patients treated with Delcath's system which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. The Company may be subject to claims against it even if the injury is due to the actions of others. For example, if the medical personnel that use Delcath's system on patients are not properly trained or are negligent in the use of the system, the patient may be injured, which may subject Delcath to claims. Were such a claim asserted, the Company would likely incur substantial legal and related expenses even if Delcath prevails 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 the Company's ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for Delcath 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 Delcath's business, financial condition and results of operations. The Company currently carries product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

#### **Risks Related to Delcath's Common Stock**

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

- fluctuations in quarterly operating results or the operating results of competitors;
- variance in financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of its markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;

- failure of its products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets served;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of competitors;
- changes in pricing policies or the pricing policies of competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by the Company or its competitors;
- potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving Delcath, its general industry or both;
- our filing for protection under federal bankruptcy laws;
- recruitment or departure of key personnel;
- changes in capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of common stock by stockholders; and
- the trading volume of Delcath's common stock.

In addition, the stock markets, in general, the OTC 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 Delcath's common stock that are unrelated or disproportionate to the operating performance of its business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of Delcath's common stock and expose it 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 the Company's financial condition and results of operations.

***The exercise price and number of certain outstanding warrants may be adjusted in future offerings.***

The 0.2 million warrants issued in the Company's February 2015, July 2015, October 2016 and February 2018 offerings are subject to an exercise price adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting Delcath's 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. In addition, to the potential dilutive effect of this provision, 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 Delcath's common stock.

***The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.***

The Company is not restricted from issuing additional shares of common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of June 14, 2019, the Company had an aggregate of 1 billion shares of common stock authorized and 18.3 million shares of common stock issued and outstanding. The 981.7 million shares of common stock not issued or outstanding include 53.4 million pre-funded warrants and 4.3 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of \$2.98. The Company may issue all of these shares without any action or approval by its shareholders. Delcath may expand its business through complementary or strategic business combinations or acquisitions of other companies and assets, and may issue shares of common stock in connection with those transactions. The market price of Delcath's common stock could decline as a result of the issuance of a large number of shares of common stock, particularly if the per share consideration received for the stock issued is less than the per share book value of Delcath's common stock or if the Company is not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share generated before the issuance of 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 investors. The Company cannot predict the size of future issuances or the effect, if any, that they may have on the market price of its common stock.

***The Company has a history of reverse splits, which have severely impacted its common stock price.***

Since Delcath's initial public offering in 2000, it has executed four reverse stock splits, for a cumulative ratio since its IPO of 1:44,800,000. Each such reverse split has resulted in an effective decline in the price of Delcath's common stock. For example, the most recent reverse split of 1:500 was effected on May 2, 2018, resulting in an opening price of \$2.50.

***Anti-takeover provisions in the Company's Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control, or make it more difficult for its stockholders to replace management.***

Certain provisions of the Company's Certificate of Incorporation and By-laws could have the effect of making it more difficult for its stockholders to replace management at a time when a substantial number of 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 its board of directors.

Furthermore, Delcath's 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. The board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of Delcath's common stock.

***The Company is subject to the risks relating to penny stocks.***

Trading in the Company's common stock is 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.

***The Company has never declared or paid any dividends to the holders of its common stock and does not expect to pay cash dividends in the foreseeable future.***

The Company currently intends to retain all earnings for use in connection with the expansion of its business and for general corporate purposes. The 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 profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by the Company's board of directors. Delcath's ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that it may enter into or by the terms of any preferred stock that may be authorized and issued. The Company does not expect to pay dividends in the foreseeable future. As a result, holders of Delcath's common stock must rely on stock appreciation for any return on their investment.



***If the Company engages in acquisitions, reorganizations or business combinations, it will incur a variety of risks that could adversely affect its business operations or its stockholders.***

The Company may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If Delcath does pursue such a strategy, the Company could, among other things:

- issue equity securities that would dilute current stockholders' percentage ownership;
- incur substantial debt that may place strains on its 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 its programs and even cease development and commercialization of CHEMOSAT and Melphalan/HDS;
- suffer the loss of key personnel, or
- merge with, or otherwise enter into a business combination with, another company in which Delcath stockholders would receive cash or shares of the other company or a combination of both on terms that certain of the Company's 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.

#### **Item 1B. Unresolved Staff Comments.**

Not applicable.

#### **Item 2. Properties.**

Delcath's 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 February 2021. The Company leases two additional spaces in the United States comprised of 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 November 2020 and March 2021 respectively. The Company has subleased the office space at 810 Seventh Avenue to unaffiliated third-parties. See Note 13 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K for more details. Delcath also owns a building comprised of approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, New York. These facilities house manufacturing, quality assurance and quality control, research and development, and office space functions. 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 comprised of approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires in August 2021. The Company has sublet a portion of this facility to an unaffiliated third-party. The Company believes substantially all of its property and equipment is in good condition and that it has sufficient capacity to meet current operational needs.

#### **Item 3. Legal Proceedings.**

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling our products or engaging in other activities.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on the Company's results of operations for that period or future periods.

As previously reported, on March 26, 2019, the Company commenced an action (the “Action”) in the Commercial Division of the Supreme Court for the State of New York, County of New York, styled as Delcath Systems, Inc., v. Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd., L1 Capital Global Opportunities Master Fund and First Fire Global Opportunities Fund LLC (Index No. 651749/2019). The Action seeks expedited equitable relief in the form of reformation and a declaratory judgement to remedy a scrivener’s error in the Series D Warrants issued in the Company’s February 2018 public offering such that those warrants do not contain a price and quantity ratchet upon a sale of Company securities at a price lower than the offering price in the February 2018 offering. The defendant, L1 Capital Global Opportunities Master Fund, settled with the Company by exchanging its Series D Warrants for Company common stock on a one-for-one basis, which is the same ratio for which other investors in the February 2018 round exchanged their Series D Warrants in December 2018. The Company and the remaining defendants in the Action, Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd. and First Fire Global Opportunities Fund LLC, entered into a settlement agreement on April 18, 2019, the full text of which is annexed as Exhibit 10.42 to this Annual Report on Form 10-K, pursuant to which such defendants surrendered the Series D Warrants and waived all rights granted to them by or in connection with the Series D Warrants and all rights afforded to them to participate in the Company’s future common stock offerings. In consideration therefor, pursuant to the settlement agreement, (i) the Company paid one-fifth of the reasonable fees and expenses of defendants’ counsel incurred in connection with the action and negotiation of the settlement agreement, the total of which shall not exceed \$50,000 (the “Settlement Fees”) and (ii) subject to the Company securing and closing certain contemplated financing, the Company agreed to pay to the defendants \$400,000 and the remaining Settlement Fees.

As previously reported, on July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County alleging breaches by the Company of Hudson Bay’s rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claimed both monetary damages (which it claims to be in excess of \$1 million) and specific performance. The Company denied any liability with respect to the claims set forth in the lawsuit. As previously reported, on January 4, 2019, the Company was notified by its litigation counsel that on December 28, 2018, the Suit was dismissed with prejudice by the filing of a Stipulation for Discontinuance in the New York State Supreme Court, New York County.

**Item 4. Mine Safety Disclosures.**

Not applicable.

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

Delcath’s common stock is traded on the OTC Markets LLC under the symbol “DCTH”.

On June 14, 2019 there were approximately 40 stockholders of record of Delcath’s common stock. The Company’s website is [www.delcath.com](http://www.delcath.com). Delcath makes available free of charge on or through its website the Company’s 10-K, 10-Q and 8-K reports, including exhibits, as soon as reasonably practicable after being filed with or furnished to the SEC.

**Dividend Policy**

The Company has never declared or paid cash dividends on its 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 current reports on Form 8-K and Quarterly Reports on Form 10-Q.

**Repurchases of Equity Securities**

None.

**Item 6. Selected Financial Data.**

Not required.

## 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 the United States, Melphalan/HDS is considered a combination drug and device product, is referred to by its chemical name and delivery system, Melphalan/HDS, and is regulated as a drug by the Federal Food and Drug Administration (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 ocular melanoma liver metastases ("mOM"), hepatocellular carcinoma ("HCC") and intrahepatic cholangiocarcinoma, a type of primary liver cancer ("ICC"). Melphalan/HDS has not been approved for sale in the United States.

In Europe, our delivery system, without the drug, is commercially available under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (marketed under the name CHEMOSAT and referred to herein as "CHEMOSAT"), where it has been used at major medical centers to treat a wide range of cancers of the liver. The current version of CHEMOSAT is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing CHEMOSAT in select markets in the European Union (the "EU") where the prospect of securing reimbursement coverage 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. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

Our primary research focus is on mOM and ICC and certain other cancers that are metastatic to the liver. Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that Melphalan/HDS and CHEMOSAT represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies. 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 Melphalan/HDS is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the "ALIGN Trial"). Our product also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select Investigator Initiated Trials.

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

While we currently utilize third parties to manufacture some components of our product, we also have our own medical device manufacturing operations for certain components of our product and assemble, label and package our products in Queensbury, New York. See the discussion in Part 1, Item 1 hereof under the caption "Manufacturing and Quality Assurance."

We commercialize our product in Europe through alliances with third parties.

## **Our Ability to Continue as a Going Concern**

The notes to our consolidated financial statements contained in this Annual Report on Form 10-K for the year ended December 31, 2018 include disclosure describing the existence of certain 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 consolidated financial statements as of December 31, 2018 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. See risk factors relating to our financial condition as well as other risk factors that we face in Part 1, Item 1A hereof under the caption “Risk Factors” above.

Our independent registered public accounting firm has issued its report dated June 14, 2019 in connection with the audit of our consolidated financial statements as of December 31, 2018 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

## **Liquidity and Capital Resources**

The Company’s future results are subject to substantial risks and uncertainties. As noted above, 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, 2018, the Company had cash and cash equivalents totaling \$2.5 million, as compared to cash and cash equivalents totaling \$4.0 million at December 31, 2017. During the year ended December 31, 2018, the Company used \$14.7 million of cash for its operating activities, which compares to \$15.4 million used for operating activities during the year ended December 31, 2017. The increase of \$0.7 million was primarily driven by an increase in operating expenses primarily related to the Company’s clinical trial effort discussed in the Overview section above. In light of recent financing activities described below, the Company believes it has sufficient capital to fund its operating activities through June 2019.

Our consolidated financial statements as of December 31, 2018 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 our development efforts and to fully commercialize our 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 selling shares of Delcath’s capital stock, borrowing money 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 and public offerings of its securities in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016 and 2018, including registered direct offerings in 2007, 2009 and 2013, “at the market” equity offering programs in 2012 and 2013, a rights offering in 2018 and by the private placement of convertible notes in 2016 and 2018. For a detailed discussion of the Company’s various sales of debt and equity securities see Notes 10 and 11 to the Company’s audited consolidated financial statements contained in this Annual Report on Form 10-K.

In October 2018, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allowed the Company to offer and sell, from time to time in one or more offerings, up to \$100.0 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. The Company has lost its Form S-3 eligibility due to the late filing of its Form 10-K for the year ended December 31, 2018.

Since the close of our most recent fiscal year, we have borrowed an aggregate of \$3.3 million from institutional investors. See Note 15 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K for a discussion of these subsequent events.

### **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, 2018:

<i>(in millions)</i>	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
<b>Operating Activities:</b>					
Future minimum lease payments, net of receipts due under subleases	\$ 2.1	\$ 0.9	\$ 1.3	\$ —	\$ —

Delcath's operating lease obligations at December 31, 2018 include:

<i>(in millions)</i>	Annual Lease Payment	Expiration
1633 Broadway, Suite 22C, NY, NY	\$ 0.5	February 2021
810 Seventh Ave, 35Fl, NY, NY <sup>1</sup>	0.5	March 2021
95 Park Road, Queensbury, NY	0.05	November 2020
19 Mervue Galway, Ireland <sup>2</sup>	0.2	August 2021
<b>Total</b>	<b>\$ 1.3</b>	

<sup>1</sup> A certain amount of expense related to the lease at 810 Seventh Ave. has been offset by two sub-leases

<sup>2</sup> A certain amount of expense related to the lease at 19 Mervue has been offset by a sub-lease

See Part I, Item 2, "Properties" and Notes 9 and 13 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K.

### **Future Capital Needs; Additional Future Funding**

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve consistent profitability. Based upon recent financing activities described above, the Company believes that it has adequate resources to fund operations through June 2019. Additional working capital will be required to continue 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, 2018; Comparisons of Results of the Years Ended December 31, 2018 and 2017**

#### **Revenue**

The Company recorded approximately \$3.4 million in product revenue during the year ended December 31, 2018. During the same period in 2017, Delcath recorded \$2.7 million in total revenue related to product sales. The year over year increase is a result of greater product sales in 2018 as Delcath continues to see increased market acceptance of its product in the EU, particularly in Germany where the establishment of the ZE code has contributed to increased treatments.

Additionally, the Company recorded approximately \$29,000 in other revenue which is related to the amortization of certain payments pursuant to a definitive licensing agreement for CHEMOSAT commercialization in Europe between the Company and medac Gesellschaft für klinische Spezialpräparate mbH ("Medac") signed on December 17, 2018 and discussed further in Part I, Item 1 under the section captioned "Market Access and Commercial Clinical Adoption" above.

The adoption of ASC 606 on January 1, 2018 had no impact on the amount and timing of revenue recognition related to product sales.

### Cost of Goods Sold

During the year ended December 31, 2018, the Company recognized cost of goods sold of approximately \$1.0 million related to product revenue of \$3.4 million as compared to cost of goods sold of approximately \$0.7 million related to product revenue of \$2.7 million in the comparable prior period.

The increase in cost of goods sold is commensurate with the increase in revenue.

### Selling, General and Administrative Expenses

For the year ended December 31, 2018, selling, general and administrative expenses increased to \$9.8 million from \$9.7 million for the year ended December 31, 2017. The slight increase reflects the Company's efforts to focus its resources on its clinical development program.

### Research and Development Expenses

For the year ended December 31, 2018, research and development expenses increased to \$19.7 million from \$10.5 million for the year ended December 31, 2017. The increase of \$9.2 million is primarily due to the ongoing efforts of the FOCUS Trial which is discussed in further detail in Part 1, Item 1 in the section captioned "Current Clinical Development Program" above.

### Other Income/Expense and Interest Expense

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

Interest expense is related to the restructuring lease liability discussed in Note 9 of the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K and the amortization of debt discounts discussed in Note 10 of the Company's audited 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.

### Change in Fair Value of Derivative Liability

For the year ended December 31, 2018, derivative instrument income increased to \$19.7 million from \$15.1 million for the year ended December 31, 2017. The increase of \$4.6 million is primarily related to the mark-to-market adjustments to the warrant liability discussed in more detail in Note 12 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K.

### Net Loss

The Company had a net loss for the year ended December 31, 2018 of \$19.2 million, a decrease of \$25.9 million, or 57.4%, compared to the net loss for the same period in 2017. This decrease is due in significant part to a \$34.7 million decrease in various non-cash items primarily related to the amortization of debt discounts and other transaction costs related to convertible notes issued in 2016 and 2018, and discussed in greater detail in Note 10 of the Company's consolidated financial statements contained in this Annual Report on Form 10-K, offset by a \$9.3 million increase in operating expenses primarily related to increased investment in clinical trial initiatives.

### Income Taxes

The Company has not recorded a provision for income taxes for the years ending December 31, 2018 and 2017, respectively, due to being in a net tax operating loss position for each of those years.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the “Tax Act”) was enacted into law and the new legislation contains several key tax provisions that affected the Company, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. The Company was required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring our U.S. deferred tax assets and liabilities as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation were expected in 2018, the Company considered the accounting of deferred tax re-measurements and the transition tax to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions. However, during the year ended December 31, 2017 the Company was able to determine a provisional amount of \$143,500 (offset by valuation allowance) and \$0, respectively, related to the deferred tax re-measurement and one-time transition tax. See Note 14 to the Company’s audited consolidated financial statements contained in this Annual Report on Form 10-K. The Company finalized its accounting of the effects of tax reform in 2018, which resulted in insignificant adjustments.

### **Application of Critical Accounting Policies**

The Company’s consolidated 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 consolidated financial statements. A summary of those significant accounting policies can be found in Note 3 to the Company’s audited consolidated 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.

Prior to ASU 2016-16, GAAP prohibited the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. ASU 2016-16 eliminates this prohibition for intra-entity transfers of assets other than inventory but retain the prohibition for intra-entity transfers of inventory. This standard is effective for public entities for fiscal years beginning after December 15, 2017. On January 1, 2012, Delcath Systems, Inc. sold a portion of its intellectual property to affiliate, 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 of the Internal Revenue Code, is a significant accounting estimate. Prior to ASU 2016-2016, the gain was deferred under 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 \$2.0 million as of December 31, 2017. The Company adopted ASU 2016-16, effective on January 1, 2018. As a result of adoption, the Company immediately recognized the \$2.0 million deferred gain and none remains as of December 31, 2018.

The Company has adopted the provisions of Accounting Standard Codification (“ASC”) 718, Stock-Based Compensation, 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, Equity-Based Payments to Non-Employees, 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, Fair Value Measurement, 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 12 to the Company's audited consolidated 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 February 2018, the Company completed the sale of 424,000 shares of its common stock, 76,000 pre-funded warrants and the issuance of warrants to purchase 1.0 million common shares (the "February 2018 Warrants") pursuant to a placement agent agreement, with net proceeds after expenses of \$4.3 million. The Company allocated an estimated fair value of \$18.3 million to the February 2018 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 February 2018 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 February 2018 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, 2018, the February 2018 Warrants were exercisable at \$10.00 per share with 0.2 million February 2018 Warrants outstanding. The February 2018 Warrants have a six-year term and are not exercisable until the first anniversary of issuance.

The proceeds allocated to the Company's issuance of warrants in 2013, 2015, 2016, 2017, and 2018 (collectively, the "Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As discussed in Note 10, the 2018 Series D Warrants were subsequently reclassified to equity. For the twelve months ended December 31, 2018, the Company recorded pre-tax derivative instrument income of \$19.7 million. The fair value of the Warrants totaled \$0.03 million at December 31, 2018. Management expects that the warrants outstanding at December 31, 2018 will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2018 was determined by using option pricing models assuming the following:

	December 31, 2018	December 31, 2017
Expected life (in years)	1.13 - 5.11	0.82 - 4.88
Expected volatility	145.7% - 265.3%	130.9% - 266.9%
Risk-free interest rates	2.5% - 2.6%	1.7% - 2.1%

**Item 8. Financial Statements and Supplementary Data**

<a href="#">Report of Marcum LLP - Independent Registered Public Accounting Firm</a>	F-1
<a href="#">Report of Grant Thornton LLP - Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets at December 31, 2018 and 2017</a>	F-3
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2017</a>	F-4
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017</a>	F-5
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-7

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of  
Delcath Systems, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Delcath Systems, Inc. (the "Company") as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### **Explanatory Paragraph - Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a working capital deficiency, has incurred losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting 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.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company's auditor since 2018.

New York, New York  
June 14, 2019

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders  
Delcath Systems, Inc.

### Opinion on the financial statements

We have audited the accompanying consolidated balance sheet of Delcath Systems Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2017, the related consolidated statement of operations, changes in stockholders’ equity, and cash flow for the year ended December 31, 2017, and the related notes (collectively referred to as the “financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flow for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### Basis for opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the auditing standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

We served as the Company’s auditor from 2015 to 2017.

/s/Grant Thornton LLP

New York, New York

March 16, 2018 (except for the matter described in Note 2, second paragraph, as to which the date is May 2, 2018)

**DELCATH SYSTEMS, INC.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 2,516	\$ 3,999
Restricted cash	1,062	1,325
Accounts receivables, net	585	317
Inventories	858	1,248
Prepaid expenses and other current assets	898	700
Total current assets	5,919	7,589
Property, plant and equipment, net	925	1,298
Total assets	<u>\$ 6,844</u>	<u>\$ 8,887</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 7,715	\$ 3,846
Accrued expenses	7,964	3,408
Convertible notes payable, net of debt discount	2,038	—
Warrant liability	33	560
Total current liabilities	17,750	7,814
Deferred revenue	3,405	—
Other non-current liabilities	628	395
Total liabilities	<u>21,783</u>	<u>8,209</u>
Commitments and contingencies		
Stockholders' Equity (Deficit)		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; 101 and 0 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$.01 par value; 1,000,000,000 shares authorized; 10,299,954 and 228,140 shares issued and 10,229,954 and 228,139 shares outstanding at December 31, 2018 and December 31, 2017, respectively*	103	2
Additional paid-in capital	328,962	325,517
Accumulated deficit	(344,054)	(324,832)
Treasury stock, at cost; 0 and 1 share at December 31, 2018 and December 31, 2017, respectively*	—	(51)
Accumulated other comprehensive loss	50	42
Total stockholders' equity (deficit)	(14,939)	678
Total liabilities and stockholders' equity (deficit)	<u>\$ 6,844</u>	<u>\$ 8,887</u>

\*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

**See Accompanying Notes to these Consolidated Financial Statements.**

**DELCATH SYSTEMS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)

	Year ended December 31,	
	2018	2017
Product revenue	\$ 3,378	\$ 2,715
Other revenue	29	—
Cost of goods sold	(1,009)	(701)
Gross profit	2,398	2,014
Operating expenses:		
Research and development expenses	19,650	10,495
Selling, general and administrative expenses	9,819	9,684
Total operating expenses	29,469	20,179
Operating loss	(27,071)	(18,165)
Change in fair value of the warrant liability, net	19,706	15,103
Gain on warrant extinguishment	—	9,613
Loss on debt extinguishment	(1,123)	(29,924)
Loss on issuance of financial instrument	(2,826)	—
Interest expense	(7,959)	(21,703)
Other income (expense)	51	(41)
Net loss	\$ (19,222)	\$ (45,117)
Other comprehensive loss:		
Foreign currency translation adjustments	\$ 8	\$ 83
Comprehensive loss	\$ (19,214)	\$ (45,034)
Common share data:		
Basic and diluted loss per share*	\$ (0.72)	\$ (3,250)
Weighted average number of basic and diluted shares outstanding*	26,705,375	14,039

\*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

**See Accompanying Notes to these Consolidated Financial Statements.**

**DELCATH SYSTEMS, INC.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**for the Years Ended December 31, 2018 and 2017**  
**(in thousands, except share data)**

	Common Stock Issued \$0.01 Par Value*		Preferred Stock Issued \$0.01 Par Value*		In Treasury*		Additional Paid-in Capital*	Accumulated Deficit	Accumulated Other Comprehensive (loss) income	Total Stockholders' Equity (Deficit)
	# of shares	Amount	# of shares	Amount	# of shares	Amount				
Balance at January 1, 2017	24	—	—	—	(1)	\$ (51)	\$ 277,790	\$ (279,188)	\$ (41)	\$ (1,490)
Compensation expense for issuance of stock options	—	—	—	—	—	—	50	—	—	50
Compensation expense for issuance of restricted stock	—	—	—	—	—	—	79	—	—	79
Issuance of common stock and rights for payments made in shares on convertible notes payable	262,462	2	—	—	—	—	40,119	—	—	40,121
Fair value of beneficial conversion feature of convertible note	—	—	—	—	—	—	4,908	—	—	4,908
Series B preferred stock dividend	—	—	—	—	—	—	—	(527)	—	(527)
Warrants exercised	736	—	—	—	—	—	19	—	—	19
Fair value of warrants exercised	—	—	—	—	—	—	2,552	—	—	2,552
Adjustment for rounding related to Nov 2017 reverse stock split	93	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(45,117)	—	(45,117)
Foreign currency translation	—	—	—	—	—	—	—	—	83	83
Balance at December 31, 2017	263,315	2	—	—	(1)	(51)	325,517	(324,832)	42	678
Compensation income related to cancellation of stock options	—	-	—	—	—	—	(40)	—	—	(40)
Compensation expense for issuance of restricted stock	164,989	2	—	—	—	—	96	—	—	98
Sale of common stock, net of expenses	5,336,665	54	—	—	—	—	10,862	—	—	10,916
Fair value of warrants issued in Feb 2018 public offering	—	-	—	—	—	—	(18,306)	—	—	(18,306)
Cashless exercise of warrants	34,467	-	—	—	—	—	—	—	—	-
Issuance of pre-funded warrants	—	-	—	—	—	—	520	—	—	520
Exercise of pre-funded warrants	3,675,516	37	—	—	—	—	(37)	—	—	-
Fair value of warrants issued with Convertible Notes	—	-	—	—	—	—	5,007	—	—	5,007
Fair value of warrants reclassified from liability to equity	—	-	—	—	—	—	4,210	—	—	4,210
Beneficial conversion feature of convertible note	—	-	—	—	—	—	44	—	—	44
Issuance of Series D Preferred Stock	—	-	101	—	—	—	1,004	—	—	1,004
Exchange of warrants for common stock	825,002	8	—	—	—	—	(8)	—	—	-
Fair value of warrants exchanged for common stock	—	-	—	—	—	—	144	—	—	144
Retirement of Treasury Stock	—	-	—	—	1	51	(51)	—	—	-
Net loss	—	-	—	—	—	—	—	(19,222)	—	(19,222)
Foreign currency translation	—	-	—	—	—	—	—	—	8	8
Balance at December 31, 2018	10,299,954	103	101	—	—	0	328,962	(344,054)	50	(14,939)

\*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

**See Accompanying Notes to these Consolidated Financial Statements.**



**DEL CATH SYSTEMS, INC.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Year ended December 31,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss	\$ (19,222)	\$ (45,117)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	(40)	50
Restricted stock compensation expense	98	79
Depreciation expense	444	310
Loss on disposal of equipment	—	18
Warrant liability fair value adjustment	(19,706)	(15,103)
Gain on warrant extinguishment	—	(9,613)
Non-cash interest income	(1)	(1)
Interest expense accrued related to convertible notes	402	—
Debt discount and deferred finance costs amortization	7,572	21,544
Loss on issuance of financial instrument	2,826	—
Loss on debt settlements and extinguishments	1,123	29,924
Changes in assets and liabilities:		
Prepaid expenses and other assets	(218)	7
Accounts receivable	(293)	108
Inventories	385	(543)
Accounts payable and accrued expenses	8,163	3,180
Deferred revenue	3,503	(32)
Other non-current liabilities	232	(209)
Net cash used in operating activities	<u>(14,732)</u>	<u>(15,398)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(76)	(524)
Net cash (used in) provided by investing activities	<u>(76)</u>	<u>(524)</u>
<b>Cash flows from financing activities:</b>		
Expenses from the release of restricted cash	—	(1,212)
Cash paid to extinguish of Series C Warrants	—	(7,876)
Net proceeds from sale of Series B and Series C preferred shares	—	2,310
Cash paid to redeem Series A and Series B preferred shares	—	(2,360)
Cash paid to redeem Series C preferred shares	—	(590)
Cash paid pursuant to Exchange Agreement	—	(804)
Net proceeds from convertible note debt financing	5,664	—
Net proceeds from sale of stock	10,917	15
Net proceeds from exercise of warrants	520	—
Net proceeds from the sale of Series D preferred shares	1,005	—
Repayment of convertible note debt	(4,870)	—
Net cash provided by (used in) financing activities	<u>13,236</u>	<u>(10,517)</u>
Foreign currency effects on cash, cash equivalents and restricted cash	(174)	67
Net decrease in cash, cash equivalents and restricted cash	<u>(1,746)</u>	<u>(26,372)</u>
<b>Cash, cash equivalents and restricted cash:</b>		
Beginning of period	5,324	31,696
End of period	<u>\$ 3,578</u>	<u>\$ 5,324</u>
<b>Supplemental non-cash activities:</b>		
Conversion of convertible notes	\$ —	\$ 40,121
Fair value of warrants issued	\$ 28,539	\$ 16,953
Cashless exercise of warrants	\$ —	\$ 2,537
Deemed dividend	\$ —	\$ 527
Fair value of warrants exercised for cash	\$ —	\$ 19

See Accompanying Notes to these Consolidated Financial Statements.

**DELCATH SYSTEMS, INC.**  
**Notes to Consolidated Financial Statements**  
**for the Years Ended December 31, 2018 and 2017**

**(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.

Our primary research focus is on ocular melanoma liver metastases (“mOM”) and intrahepatic cholangiocarcinoma (“ICC”) and certain other cancers that are metastatic to the liver. Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that Melphalan/HDS and CHEMOSAT represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Our clinical development program for Melphalan/HDS is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the “FOCUS Trial”), a global registration clinical trial that is investigating objective response rate in mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the “ALIGN Trial”). Our product also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select Investigator Initiated Trials.

While we currently utilize third parties to manufacture some components of our product, we also have our own manufacturing operations for certain components of our product and assemble and package our products in Queensbury, New York. See the discussion in Part 1, Item 1 under the caption “Manufacturing and Quality Assurance” above.

We commercialize our product in Europe through alliances with third parties.

**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. As shown in the accompanying financial statements during the year ended December 31, 2018, the Company incurred net losses of \$19.2 million and used \$14.7 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 the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, it 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 Delcath is not able to continue as a going concern, it is likely that holders of its 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. At December 31, 2018, management believed that its capital resources were adequate to fund operations through March 2019. Additional working capital will be required to continue operations. 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. See Note 15 of these notes to the Company’s audited consolidated financial statements relating to subsequent events.

**(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.

***Reverse Stock Splits***

All share numbers presented in this footnote reflect a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

**(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.

***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.

***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. The Company evaluates property, plant and equipment for impairment periodically to determine if changes in circumstances or the occurrence of events suggest the carrying value of the asset or asset group may not be recoverable. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

***Derivative Instrument Liability***

The Company accounts for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, Derivatives and Hedging, 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

**DELCATH SYSTEMS, INC.**  
**Notes to Consolidated Financial Statements**  
**for the Years Ended December 31, 2018 and 2017**

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, 2018 and 2017, the Company did not have any derivative instruments that were designated as hedges.

***Fair Value Measurements***

The Company adheres to ASC 820, Fair Value Measurement, 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 is generated from proprietary and partnered product sales and license and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services. 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.

We may enter into contracts with partners that contain multiple elements such as licensing, development, manufacturing and commercialization components. These arrangements are often complex and we may receive various types of consideration over the life of the arrangement, including: up-front fees, reimbursements for research and development services, milestone payments, payments on product shipments, margin sharing arrangements, license fees and royalties.

**DELCATH SYSTEMS, INC.**  
**Notes to Consolidated Financial Statements**  
**for the Years Ended December 31, 2018 and 2017**

Our results of operations for reporting periods beginning on or after January 1, 2018 are presented under ASC 606, Revenue from Contracts with Customers, while prior period amounts, as reported, are not adjusted. The effects of the adoption of the new standard in 2018 were not material to our consolidated financial statements. In assessing our revenue arrangements in accordance with ASC 606, Revenue from Contracts with Customers, we must identify the contract, determine the transaction price including an estimation of any variable consideration we expect to receive in connection with the contract, identify the promises of goods or services to the customer and each distinct performance obligation, allocate the transaction price to each of the performance obligations, and recognize revenue when or as the performance obligations are satisfied. Each of these steps in the revenue recognition process requires management to make judgements and/or estimates. The most significant judgements and estimates involve the determination of variable consideration to be included in the transaction price. Variable consideration is recognized at an amount we believe is not subject to significant reversal and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed. We believe this provides a reasonable basis for recognizing revenue, however, actual results could differ from estimates and significant changes in estimates could impact our results of operations in future periods.

***Deferred Revenue***

License fees and milestones received in exchange for the grant of a license for the commercialization of CHEMOSAT are generally recognized over the development period, as the license is considered distinct from the delivery of product. Milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved.

***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, Stock-Based Compensation, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, Equity-Based Payments to Non-Employees, 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 expenses its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

**DELCATH SYSTEMS, INC.**  
**Notes to Consolidated Financial Statements**  
**for the Years Ended December 31, 2018 and 2017**

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 14 for additional information.

***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, 2018 and 2017:

<i>(in thousands, except share data)</i>	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Net loss - basic	\$ (19,222)	\$ (45,117)
Preferred stock dividends	—	(527)
Net loss - diluted	<u>\$ (19,222)</u>	<u>\$ (45,644)</u>
Weighted average shares outstanding - basic	<u>26,705,375</u>	<u>14,039</u>
Weighted average shares outstanding - diluted	<u>26,705,375</u>	<u>14,039</u>
Net loss per share - basic	\$ (0.72)	\$ (3,250)
Net loss per share - diluted	\$ (0.72)	\$ (3,250)

In the third quarter of 2017, the Company issued Series B Preferred Shares. A portion of the redemption price of the Series B Preferred Shares was accounted for as a deemed dividend.

**DELCATH SYSTEMS, INC.**  
**Notes to Consolidated Financial Statements**  
**for the Years Ended December 31, 2018 and 2017**

At December 31, 2018, the Company has 61.3 million pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation at December 31, 2018:

	<b>December 31, 2018</b>
Weighted average shares issued	2,738,944
Weighted average pre-funded warrants	23,966,431
Weighted average shares outstanding	<u>26,705,375</u>

For the years ended December 31, 2018 and 2017 the following potentially dilutive securities were excluded from the computation of diluted earnings per share because their effects would be antidilutive.

Shares excluded from the computation of diluted earnings per share:

	<b>2018</b>	<b>2017</b>
Common stock warrants - equity	4,202,909	14,049
Common stock warrants - liability	189,029	—
Assumed conversion of convertible notes	2,576,203	—
Total	<u>6,968,141</u>	<u>14,049</u>

**Segment Information**

The Company currently operates in one business segment, which is the development and commercialization of Melphalan/HDS and CHEMOSAT. 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 statements 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. The majority of the foreign subsidiaries revenues and operating expenses are denominated in Euros. The reporting currency for the Company is the United States Dollar ("USD"). Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

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

**Recently Adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, 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 has adopted this guidance.

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In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), which 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 was permitted, including interim periods within those fiscal years provided that those electing early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The Company has adopted this guidance.

In October 2016, the FASB issues ASU 2016-16 which simplifies the income tax consequences of intra-entity transfers other than inventory. Prior to ASU 2016-16, GAAL prohibited the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. ASU 2016-16 eliminates this prohibition for intra-entity transfers of assets other than inventory but retains the prohibition for intra-entity transfers of inventory. This standard is effective for public entities for fiscal years beginning after December 15, 2017. The Company has adopted this guidance. The adoption did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which 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 are also 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 was permitted. The Company adopted this standard.

***SEC Disclosure Update and Simplification***

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The adoption did not have a material impact on the Company's consolidated financial statements.

***Recent Accounting Standards to be Adopted***

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), superseding ASC Topic 840, Leases. ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements that allows entities to apply the provisions of the new standard at the effective date (e.g. January 1, 2019), as opposed to the earliest period presented under the modified retrospective transition approach (January 1, 2017) and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company is currently evaluating the effect the guidance will have on our audited consolidated financial statements.



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In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815). This guidance was intended to reduce the complexity associated with the issuer's accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the Board determined that a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. In addition, the Board re-characterized the indefinite deferral of certain provisions of Topic 480 to a scope exception. The re-characterization has no accounting effect. ASU 2017-11 is effective for public entities for fiscal years beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company's consolidated financial statements.

**(4) Restricted Cash**

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded in *Restricted Cash* on the balance sheet. Restricted cash does not include required minimum balances.

<i>(in thousands)</i>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Cash and cash equivalents	\$ 2,516	\$ 3,999
Convertible Notes	—	238
Letters of credit	1,012	1,012
Security for credit cards	50	75
<b>Total cash, cash equivalents and restricted cash shown in the statement of cash flows</b>	<b>\$ 3,578</b>	<b>\$ 5,324</b>

**(5) Inventories**

Inventories consist of:

<i>(in thousands)</i>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Raw materials	\$ 358	\$ 298
Work-in-process	500	721
Finished goods	—	229
<b>Total Inventory</b>	<b>\$ 858</b>	<b>\$ 1,248</b>

**(6) Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets include the following:

<i>(in thousands)</i>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Insurance premiums	\$ 140	\$ 421
Financing costs	—	70
Security deposit	51	50
Income tax and VAT receivable	579	29
Other <sup>1</sup>	128	130
<b>Total prepaid expenses and other current assets</b>	<b>\$ 898</b>	<b>\$ 700</b>

<sup>1</sup>Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at December 31, 2018 and 2017.

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**(7) Property, Plant, and Equipment**

Property, plant, and equipment consists of:

<i>(in thousands)</i>	December 31, 2018	December 31, 2017	Estimated Useful Life
Buildings and land	\$ 589	\$ 579	30 years - Buildings
Enterprise hardware and software	1,742	1,744	3 years
Leaseholds	1,701	1,705	Lesser of lease term or estimated useful life
Equipment	1,002	971	7 years
Furniture	198	175	5 years
Property, plant and equipment, gross	5,232	5,174	
Accumulated depreciation	(4,307)	(3,876)	
Property, plant and equipment, net	<u>\$ 925</u>	<u>\$ 1,298</u>	

Depreciation expense for the years ended December 31, 2018 and 2017 was \$0.4 million, \$0.3 million, respectively.

**(8) Current Accrued Expenses**

Current accrued expenses include the following:

<i>(in thousands)</i>	December 31, 2018	December 31, 2017
Clinical trial expenses	\$ 4,530	\$ 869
Compensation, excluding taxes	1,785	1,124
Professional fees	190	221
Short-term portion of lease restructuring	184	209
Other <sup>1</sup>	1,275	985
Total accrued expenses	<u>\$ 7,964</u>	<u>\$ 3,408</u>

<sup>1</sup>Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2018 and 2017.

**(9) Restructuring Expenses**

In order to help reduce operating costs and more appropriately align its office space with the 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, 2018, the total remaining lease restructuring liability for its leased office space was approximately \$0.4 million, of which approximately \$0.2 million and \$0.2 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, 2018:

<i>(in thousands)</i>	Lease Liability
Reserve balance at December 31, 2017	\$ 604
Charges	—
Payments/Utilizations	(208)
Reserve balance at December 31, 2018	<u>\$ 396</u>

**(10) Convertible Notes Payable**

**(Secured Convertible Notes and related Common Stock Purchase Warrants)**

On June 4, 2018, July 21, 2018, August 29, 2018, and September 21, 2018, the Company issued 8% senior secured convertible notes (collectively, “the Notes”) to investors with aggregate principal of \$9.4 million and maturity dates between December 2018 and March 2021. 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. At December 31, 2018, the Notes were convertible at \$1.75 per share subject to customary terms.

In April 2019, the Company received notices of default from the investors in the Notes.

In connection with the issuance of the Notes, the Company also issued 4.2 million Series D Warrants with exercise prices ranging from \$1.75 - \$4.00 and 65.0 million Pre-Funded Series D Warrants with a purchase price of \$0.01. The warrants expire 5 years from the date they could first be exercised. The provisions in the Series D Warrants and Pre-Funded Series D Warrants issued in June 2018 required the Company to initially account for the warrants as derivative liabilities. The warrants were valued at \$5.1 million. As a result, the Company recognized a discount to debt of \$2.3 million and a loss on issuance of a financial instrument of \$2.8 million.

The Company valued the June 2018 Series D Warrants using the following inputs:

	<b>June 2018 Series D Warrant</b>	<b>June 2018 Pre- Funded Series D Warrants</b>
Contractual life	5.0	5.5 - 6.5
Expected volatility	194.10%	215.0% - 389.0%
Risk-free interest rates	2.78%	2.13% - 2.30%

*First Amendment to June 2018 Series D Warrants*

In July 2018, the Company and the investor from the June 2018 transaction amended the June 2018 Pre-Funded Series D Warrants so that they are exercisable as of July 20, 2018 and the Company may redeem them at any time the Notes are no longer outstanding and the Company is not in default. The Company and the investor from the June 2018 transaction also amended the definition of a Fundamental Transaction in the June 2018 Warrants. This amendment resulted in \$4.2 million related to the fair value of the June 2018 Warrants being reclassified from a liability to equity.

*Amendment to June 2018 and July 2018 Notes and Pre-Funded Warrants*

In August 2018, the Company amended its June 2018 Notes and July 2018 Notes such that the conversion price was reduced to \$1.75, interest shall accrue until maturity, and the first \$2.5 million and 50% of any subsequent financings shall be used to satisfy the Company’s obligations under the Notes. Effective the same date, the Company also amended its Pre-Funded Warrants such that the total number of June 2018 Pre-Funded Warrants was increased from 13.0 million to 22.2 million and the total number of July 2018 Pre-Funded Warrants was increased from 9.2 million to 15.8 million. This amendment was accounted for as an extinguishment of debt as the change in cash flows exceeded 10%. The original June 2018 and July 2018 notes were written off and the amended June 2018 and July 2018 Notes were recorded at fair value as of the date of this amendment. The Company recorded \$1.1 million loss on debt extinguishment related to this amendment.

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The following table provides a summary of the Notes by their maturity dates (absent provisions of default):

<i>(in millions)</i>	<u>Interest rate</u>	<u>Conversion price</u>	<u>Principal</u>	<u>Unamortized Discount</u>	<u>Carrying value</u>
December 4, 2018	8.0%	\$ 1.75	\$ 1.7	\$ —	\$ 1.7
March 1, 2019	8.0%	1.75	0.6	(0.5)	0.1
March 21, 2019	8.0%	1.75	0.4	(0.2)	0.2
December 4, 2019	8.0%	1.75	0.9	(0.9)	—
March 1, 2020	8.0%	1.75	0.8	(0.8)	—
March 21, 2020	8.0%	1.75	0.1	(0.1)	—
Total Convertible Notes Payable, net			<u>\$ 4.5</u>	<u>\$ (2.5)</u>	<u>\$ 2.0</u>

**(11) Stockholders' Equity**

***Preferred Stock Issuances***

*Series D Preferred Stock*

On November 5, 2018, the Company's Board authorized the establishment of a new series of preferred stock designated as Series D Preferred Stock, \$0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock which was filed with the State of Delaware on November 5, 2018. On November 6, 2018 and November 30, 2018, the Company entered into a securities purchase agreements with an institutional investor which had purchased 101 shares of Series D Preferred Stock. At issuance, the Series D Preferred Stock would convert to 1,655,738 common shares.

On March 29, 2019, the Company exchanged all of its Series D Preferred Stock (with a stated value of \$1,160,000) and received \$400,000 in proceeds and issued a senior secured promissory note to an investor with a principal amount of \$1,560,000. As a result, the Series D Preferred Stock is no longer outstanding.

***Stock and Warrant Issuances***

*February 2018 Financing*

In February 2018, the Company completed the sale of 424,000 shares of its common stock, 76,000 pre-funded warrants and the issuance of warrants to purchase 1.0 million common shares (the "February 2018 Warrants") pursuant to a placement agent agreement, with net proceeds after expenses of \$4.3 million. The February 2018 Warrants are exercisable one year after the anniversary date of their issuance. At December 31, 2018, the February 2018 Warrants were exercisable at \$10.00 per share with 0.2 million warrants outstanding. The Company allocated an estimated fair value of \$18.3 million to the February 2018 Warrants. The Company valued the February 2018 Warrants using the following inputs: exercise price of \$10.00; contractual term of six years; volatility of 122.68% and risk-free rate of approximately one percent. Due to certain price protection features in the agreement, the February 2018 Warrants were accounted for as a derivative liability at issuance and will be subsequently marked to market through the statement of operations.

*September 2018 Rights Offering*

In September 2018, the Company completed the sale of 4,667,811 shares of its common stock, with net proceeds after expenses of approximately \$7.0 million. The rights offering was made pursuant to a Registration Statement on Form S-1 that was made effective on August 3, 2018.

*December 2018 Warrant Exchange*

In December 2018, the Company entered into exchange agreements with several institutional investors with respect to their November 2017 Warrants and February 2018 Warrants. The Company issued to the investors 0.8 million shares of Common Stock (the "Exchange Shares") in exchange for the Existing Warrants (the "Exchange"). The Exchange was made in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

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*Pre-Funded Series D Warrant Exercises*

3.7 million Pre-Funded Series D Warrants were exercised during 2018.

In October 2018, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allows the Company to offer and sell, from time to time in one or more offerings, up to \$100.0 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. The Company has lost its Form S-3 eligibility due to the late filing of its Form 10-K for the year ended December 31, 2018.

**Stock Incentive Plans**

As a result of the May 2, 2018 reverse stock split, the Company's Stock Incentive Plan has no active grants and no further shares available to be granted.

As previously reported, on February 1, 2019 the Board of Directors of the Company adopted the Company's 2019 Equity Incentive Plan (the "2019 Plan"), pursuant to which 1,500,000 shares of common stock of the Company are available for grants through February 1, 2029 to the Company's employees, directors and consultants. On February 1, 2019, options to purchase 1,250,000 shares of common stock, at an exercise price of \$0.281 per share, were granted under the 2019 Plan to certain executive officers and employees of the Company. The stock options are vesting over a period of one year commencing from the date of grant in twelve equal monthly increments commencing on the one month anniversary of the grant date. The stock options carry a ten year term and expire on February 1, 2029.

For the years ended December 31, 2018 and December 31, 2017, the Company recognized compensation income of \$0.04 million and \$0.05 million, respectively, related to stock options granted to employees.

For the years ended December 31, 2018 and December 31, 2017, the Company recognized compensation expense of approximately \$0.1 million and \$0.1 million, respectively, related to restricted stock granted to employees and consultants.

**Warrants**

The Company issued warrants as part of its offerings in 2013, 2015, 2016 and 2018 as well as part of its issuance of convertible notes in 2016 and 2018 and an exchange agreement in 2017. 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, 2017	78	\$281,750 - \$19,712,000	\$ 910,000	5.59
Warrants issued	14,256		2,299	
Warrants exercised	(246)		4,221	
Warrants expired	(39)		845,250	
Outstanding at December 31, 2017	14,049	\$1,225 - \$19,712,000	\$ 1,569	4.88
Warrants issued in Feb 2018 registered direct offering	1,076,002		9.33	
Warrants issued with convertible notes	69,169,756		0.18	
Exercised	(4,574,529)		1.79	
Expired	(9)		19,712,000	
Outstanding at December 31, 2018	<u>65,685,269</u>	\$0.01 - \$10.00	\$ 0.22	5.75

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**(12) Derivative Financial Instruments**

Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2018 was determined by using option pricing models assuming the following:

	December 31, 2018	December 31, 2017
Expected life (in years)	1.13 - 5.11	0.82 - 4.88
Expected volatility	145.7% - 265.3%	130.9% - 266.9%
Risk-free interest rates	2.5% - 2.6%	1.7% - 2.1%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 and 2017, 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**

<i>(in thousands)</i>	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
	2018	2017	2018	2017	2018	2017	2018	2017
<b>Liabilities</b>								
Derivative instrument liabilities	\$ —	\$ —	\$ —	\$ —	\$ 33	\$ 560	\$ 33	\$ 560

For the twelve months ended December 31, 2018 and December 31, 2017 there were no transfers in or out of Level 1, 2 or 3 inputs.

The table below presents the activity within Level 3 of the fair value hierarchy for the twelve months ended December 31, 2018:

**Fair Value Measurements Using Significant Unobservable  
Inputs (Level 3)**

<i>(in thousands)</i>	Warrant Liability
Balance at January 1, 2017	\$ 18,751
Total change in the liability included in earnings	(15,103)
Extinguishment of convertible note warrant	(17,489)
Fair value of warrants issued	16,953
Fair value of warrants exercised	(2,552)
Balance at December 31, 2017	560
Fair value of warrants issued	23,533
Total change in the liability included in earnings	(19,706)
Reclass from liability to equity	(4,210)
Fair value of warrants exchanged	(144)
Balance at December 31, 2018	\$ 33

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**(13) 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 \$1.0 million in 2015, \$1.0 million in 2016, and \$1.2 million in 2017-2020. As discussed in Note 9, the Company has sub-leased this office space.

In August 2011, Delcath Systems Ltd. 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, 2011. The Lease provides for fixed annual lease amounts payable in advance in equal quarterly installments. The remaining annual lease amount is \$0.2 million. Delcath Systems Ltd. is also required to pay for customary building operating expenses. Delcath Systems Ltd.'s payment obligations and performance of the Lease are guaranteed by Delcath. The Company has sub-leased a portion of this facility.

In September 2018, the Company entered into an amendment (the "1633 Sublease Amendment") to a sub-lease agreement executed in March 2016 (the "1633 Sublease") for approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term began in April 2016 and under the terms of the 1633 Sublease Amendment is extended through February 2021 and provides for total annual base rent of \$0.5 million.

In January 2019, the Company entered into an amendment (the "Park Road Lease Amendment") to a lease agreement entered into in October 2018 (the "Park Road Lease") for approximately 6,000 square feet of space located at 95-97 Park Road in Queensbury, New York. Under the terms of the Park Road Lease Amendment, the original two year term which began on October 31, 2018 was extended through November 2020 and provides for total annual base rent of \$50,000 per year.

Future minimum lease payments, net of receipts due under the terms of subleases, under all operating leases at December 31, 2018 are as follows:

<i>(in thousands)</i>	<b>Future Lease Payment</b>
2019	885
2020	916
2021	348
	<u>\$ 2,149</u>

For the years ended December 31, 2018 and 2017 rent expense, net of receipts under the terms of subleases, totaled approximately \$0.6 million and \$0.6 million, respectively.

***Litigation***

As previously reported, on March 26, 2019, the Company commenced an action (the "Action") in the Commercial Division of the Supreme Court for the State of New York, County of New York, styled as Delcath Systems, Inc., v. Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd., L1 Capital Global Opportunities Master Fund and First Fire Global Opportunities Fund LLC (Index No. 651749/2019). The Action seeks expedited equitable relief in the form of reformation and a declaratory judgement to remedy a scrivener's error in the Series D Warrants issued in the Company's February 2018 public offering such that those warrants do not contain a price and quantity ratchet upon a sale of Company securities at a price lower than the offering price in the February 2018 offering. The defendant, L1 Capital Global Opportunities Master Fund, settled with the Company by exchanging its Series D Warrants for Company common stock on a one-for-one basis, which is the same ratio for which other investors in the February 2018 round exchanged their Series D Warrants in December 2018. The Company and the remaining defendants in the Action, Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd. and First Fire Global Opportunities Fund LLC, entered into a settlement agreement on April 18, 2019, the full text of which is annexed as Exhibit 10.42 to this Annual Report on Form 10-K, pursuant to which such defendants surrendered the Series D Warrants and

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waived all rights granted to them by or in connection with the Series D Warrants and all rights afforded to them to participate in the Company's future common stock offerings. In consideration therefor, pursuant to the settlement agreement, (i) the Company paid one-fifth of the reasonable fees and expenses of defendants' counsel incurred in connection with the Action and negotiation of the settlement agreement, the total of which shall not exceed \$50,000 (the "Settlement Fees") and (ii) subject to the Company securing and closing certain contemplated financing, the Company agreed to pay to the defendants \$400,000 and the remaining Settlement Fees.

As previously reported, on July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County alleging breaches by the Company of Hudson Bay's rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claimed both monetary damages (which it claims to be in excess of \$1 million) and specific performance. The Company denied any liability with respect to the claims set forth in the lawsuit. As previously reported, on January 4, 2019, the Company was notified by its litigation counsel that on December 28, 2018, the Suit was dismissed with prejudice by the filing of a Stipulation for Discontinuance in the New York State Supreme Court, New York County.

On May 9, 2018, the Company received a Demand Letter from a vendor for an outstanding balance owed at that time of \$2.1 million. The Company has worked with the vendor since that time to establish a payment plan for the balance owed.

***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 \$0.9 million which will expire in February 2021 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 \$0.1 million which will expire with the sublease in February 2021.

**(14) Income Taxes**

Income (loss) before income taxes consists of:

<i>(in thousands)</i>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Domestic	\$ (12,961)	\$ (41,313)
Foreign	(6,261)	(3,804)
Income (loss) before taxes	<u>\$ (19,222)</u>	<u>\$ (45,117)</u>



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

<i>(in thousands)</i>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Income taxes using U.S federal statutory rate	\$ (4,037)	\$ (15,340)
Tax Cuts and Jobs Act	—	143
Nondeductible interest	2,273	6,912
Loss on extinguishment of debt	236	10,174
Loss of tax benefit of federal net operating loss carryforwards	(588)	5,067
Loss of tax benefit of state net operating loss carryforwards	1,040	1,373
Loss of tax benefit of federal tax credit carryforwards	495	324
Amortization of gain on IP migration	—	767
State income taxes, net of federal benefit	(2,355)	(1,339)
Foreign rate differential	1,166	1,196
Valuation allowance	6,323	(1,423)
Derivative charge	(4,138)	(8,403)
Stock option exercises and cancellations	215	841
Research and development costs	(636)	(295)
Other	6	3
	<u>\$ —</u>	<u>\$ —</u>

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

<i>(in thousands)</i>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>Deferred tax assets:</b>		
Employee compensation accruals	\$ —	\$ 292
Accrued liabilities	519	353
Research tax credits	161	17
Other	60	34
Net operating losses	10,624	5,289
Total deferred tax assets	<u>11,364</u>	<u>5,985</u>
<b>Deferred tax liabilities:</b>		
Beneficial conversion feature	—	—
Other	—	13
Total deferred tax liabilities	<u>—</u>	<u>13</u>
Valuation allowance	11,364	5,972
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2018 and 2017 the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately \$230.0 million and \$211.3 million respectively. A significant portion of the federal amount is subject to an annual limitation as low as \$27,500 as a result of changes in the Company's ownership in May 2003, November 2016, and multiple dates throughout 2017 and 2018, 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, November 2016 and multiple 2017 and 2018 ownership changes, approximately \$208.1 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately \$21.9 million of net operating loss carryforwards remains available to offset future federal taxable income, of which \$1.7 million will expire between 2019 and 2037 and \$20.2 million will have an unlimited carryforward period as a result of the Tax Cuts and Jobs Act.

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In addition, the Company's state net operating losses are also subject to annual limitations that generally follow the federal Section 382 provisions (with the exception of Connecticut), adjusted for each state's respective income apportionment percentages. As of December 31, 2018 and 2017, the Company had net operating loss carryforwards for state and city income tax purposes between approximately \$27.3 million and \$167.3 million and between approximately \$27.3 million and \$150.3 million, respectively, which expire through 2038. As a result of the 382 limitations, approximately \$157.2 million and \$141.5 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 \$10.1 million and \$10.1 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2018 and 2017 the Company had a net operating loss carryforward for foreign income tax purposes of \$25.2 million and \$25.0 million, respectively, which have indefinite carryforward periods. As of December 31, 2018 and 2017, the Company had federal research and development tax credit carryforwards of approximately \$5.0 million and \$4.3 million respectively, which expire through 2038. As a result of the section 382 limitations, all but \$0.2 million of the tax credit carryforwards is expected to expire unutilized.

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 \$5.4 million and decreased by \$1.1 million in 2018 and 2017, respectively. The change in valuation allowance is as follows:

<i>(in thousands)</i>	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Beginning balance	\$ 5,972	\$ 7,094
Charged to costs and expenses	6,323	(1,423)
Charged to additional paid-in capital	—	—
Charged to retained earnings	(834)	—
Charged to other comprehensive income	(97)	301
Ending balance	<u>\$ 11,364</u>	<u>\$ 5,972</u>

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "Act"). The Act, which is also commonly referred to as "U.S. tax reform", significantly changes U.S. corporate income tax laws by, among other provisions, reducing the maximum U.S. corporate income tax rate from 35% to 21% starting in 2018. During the year ended December 31, 2017, the Company reduced deferred tax assets by a provisional amount of \$143,500, offset by a corresponding reduction to its valuation allowance, as a result of the re-measurement of deferred tax assets and liabilities from its 34% effective rate under existing law to the new lower statutory rate of 21%. The Company finalized its accounting of the effects of tax reform in 2018, which resulted in insignificant adjustments.

The Act also requires a mandatory one-time inclusion of the deferred foreign income of controlled foreign corporations. The one-time transition tax is based on Delcath's total post-1986 earnings and profits (E&P) for which the Company has previously deferred from U.S. income taxes. During the year ended December 31, 2017, the Company's reasonable estimate resulted in no provisional amount for the one-time transition tax liability, as the Company's international subsidiaries are expected to have a cumulative deficit in E&P. As the Company's international subsidiaries have a cumulative deficit in earnings and profits, the Company did not anticipate being affected by the mandatory inclusion provisions of the Act. The Company finalized its calculation of the total post-1986 foreign E&P (including deficits) for these foreign subsidiaries during 2018 and was not impacted by the mandatory inclusion provisions of the Act.

On December, 22, 2017, Staff Accounting Bulletin 118 was issued due to the complexities involved in accounting for the recently enacted Act. SAB 118 requires the Company to include in its financial statements a reasonable estimate of the impact of the Act on earnings to the extent such estimate has been determined. Accordingly, the U.S. provision for income tax for December 31, 2017 was based on the reasonable estimate guidance provided by SAB 118. The Company finalized the impact from the Act and recorded insignificant adjustments.

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The Company complies with the provisions of ASC 740-10, Income Taxes, 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 than 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 and therefore has not included a tabular rollforward of unrecognized tax benefits. As there are no uncertain tax positions recognized, interest and penalties have not been accrued.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The Company has not been audited by 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, 2015; tax years ending December 31, 2015 through December 31, 2018 remain open to examination. The Republic of Ireland is the Company's only significant foreign jurisdiction. The Company is no longer subject to Ireland tax examination for tax years ending prior to December 31, 2014 (as Ireland has not initiated an audit of 2013 as of December 31, 2018); tax years ending December 31, 2014 through December 31, 2018 remain open to examination. However, the Company's tax years December 31, 1998 through December 31, 2018 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.

**(15) Subsequent Events**

Since January 1, 2019, the Company has issued 7.9 million shares pursuant to exercises of Pre-Funded Series D Warrants.

As previously reported, in January 2019, the Company terminated Backstop Commitment Purchase Agreements with four institutional investors, by their mutual agreement. The Company and such institutional investors entered into Backstop Commitment Purchase Agreements in connection with a rights offering conducted by the Company that closed in September 2018 in which the Company proposed to raise up to \$50 million by distributing, at no charge, to holders of its common stock non-transferable rights to subscribe for and purchase shares of the Company's common stock at a price of \$1.75 per share (the "Subscription Price"). Pursuant to the Backstop Commitment Purchase Agreements, such institutional investors agreed to purchase, at the Subscription Price, shares not issued in the rights offering following the expiration of the rights offering subscription period, subject to certain conditions, including the requirement that the closing price of a share of the Company's common stock as reported by the OTCQB or higher market for each of the five business days immediately preceding a purchase exceeded the Subscription Price. The Backstop Commitment Purchase Agreements were terminated by mutual agreement of the parties thereto due to the fact that the closing price of the Company's common stock had not exceeded the Subscription Price since October 1, 2018 and, thus, the institutional investors had no obligation to purchase shares.

On March 29, 2019, the Company exchanged all of its Series D Preferred Stock (with a stated value of \$1,160,000) and received \$400,000 in proceeds and issued a senior secured promissory note to an investor with a principal amount of \$1,560,000. The note is due on April 1, 2020, bears interest at 8% per annum and is nonconvertible.

On April 19, 2019, April 26, 2019, May 9, 2019 and May 23, 2019, the Company borrowed an aggregate \$3.3 million from two institutional investors and issued promissory notes to the investors. The promissory notes have an aggregate principal amount of \$3.3 million, bear interest at the rate of 8% per annum and are due six months from the issuance of each note. The promissory notes are nonconvertible. The notes contain standard events of default and remedies therefor. The Company's obligations under the promissory notes to the institutional investor are secured by a lien on the Company's assets.

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On June 6, 2019, the Company entered into an agreement with two institutional investors, pursuant to which the investors agreed to transfer and surrender to the Company for cancellation of 3.9 million Series D Warrants and 53.4 million Pre-Funded Series D Warrants. Under the terms of the Purchase Agreement, the investors agreed to defer the payment of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants and, accordingly, the Company agreed to sell and issue to the investors 8% Senior Secured Promissory Notes in an aggregate principal amount of \$2 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants.

## **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, 2018 (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, 2018 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, 2018. 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, 2018, 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.

**Information About Directors.** The following table sets forth certain information about our directors.

Name	Age	Position with Delcath	Director Since
William D. Rueckert	66	Director	2014
Marco Taglietti, M.D.	59	Director	2014
Roger G. Stoll, Ph.D.	76	Chairman	2008
Jennifer K. Simpson, Ph.D.	50	Director	2015

*William D. Rueckert* was appointed as a Director in December 2014. Mr. Rueckert has served on many public and private corporate boards in both the life science and banking industries. He is currently President of Oyster Management Group, LLC, an investment partnership specializing in community banking. From 2007 until 2012 he served on the board of Novogen Ltd. (ASX, NASDAQ) a biotechnology company based in Sydney, Australia. He acted as Chairman from 2010 until 2012, and as acting CEO led the restructuring of the company, spinning off its major subsidiary, Marshall Edwards, Inc. (now MEI Pharma, Inc. NASDAQ.) He is currently a director of MEI Pharma, Inc. (NASDAQ), a San Diego based company that is developing novel oncology therapies. Until its sale to H. Lundbeck A/S, he was a director of Chelsea Therapeutics International, Ltd. (NASDAQ) whose drug candidate, Northera, was approved by the FDA in 2014. He has also served on the boards of several banks including Westport Bank and Trust, Lafayette American Bank and Hudson United Bank (all NASDAQ.) He currently serves on the board of Fairfield County Bank, a mutually owned, community bank based in Ridgefield, Connecticut, and Bleachers, Inc., a privately held company that streams live and archived sports and entertainment events from independent schools. Among his civic associations, Mr. Rueckert is a Director and President of the Cleveland H. Dodge Foundation, Co-Chairman of the Board of Trustees of Teachers College, Columbia University, a Director of the Y Retirement Fund, a Trustee of International House, an Emeritus Director of the YMCA of Greater New York, a Trustee of the American University of Beirut and a Director of Wave Hill, Inc. He earned a BA in Spanish in 1977 from the University of New Hampshire. The Nominating Committee considered Mr. Rueckert's experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Mr. Rueckert should serve as director of Delcath.

*Roger G. Stoll, PhD.* was appointed as a director of in December 2008. Executive Chairman in September, 2014 and has served as Chairman of the Board since October 1, 2015. From 2002 to 2010 he served as Chairman and Chief executive Officer of Cortex Pharmaceuticals, Inc. In August of 2010 he was appointed Executive Chairman of the board Cortex and retired in 2012. From 2001 to 2002 he was a consultant to several east coast venture capital firms and startup ventures. From 1998 to 2001, he was Executive Vice President of Fresenius Medical Care-North America, in charge of the dialysis products division and the diagnostic business units, which included hemodialysis machines, dialysis filters, dialysate solutions, and attendant devices used in the dialysis procedure. From 1991 - 1998, Dr. Stoll was Chief Executive of Ohmeda, a global leader in anesthetic agents, critical care drugs and related operating room devices with sales of \$1 billion annually. From 1994 until the sale of Ohmeda in 1998, he was also a member of the board of directors of The BOC Group,plc in London. From 1986 - 1991, Dr. Stoll held several positions of increasing responsibility at Bayer, AG including, Chief Administrative Office, President of Consumer Healthcare business unit, and Executive Vice-President and General Manager for its worldwide Diagnostic Business Group w which included the acquisition of The Technicon Company and globally integrating the Bayer and Technicon business units. This resulted in a global diagnostic business in excess of \$1billion in sales annually. Prior to that he worked for American Hospital Supply Corporation, where he rose from Director of Clinical Pharmacology to President of the American Critical Care drug division of AHSC. He began his pharmaceutical career at the Upjohn Company working in drug metabolism and pharmacokinetic studies in a clinical development unit in 1972. Dr. Stoll obtained his BS in Pharmacy degree at Ferris State University, his PhD in Biopharmaceutics and drug metabolism at the University of Connecticut and was a post-doctoral fellow for two years at the University of Michigan. He served on the board of Agensys, Inc from 2003 until its sale to Astellas in late 2007. Also on the board of Questcor Pharmaceuticals, and Chelsea Therapeutics until it was acquired in 2008 by Lundbeck A/S. From 1991 to 2002 he also served on the board of directors of St.Jude Medical. He also served on the boards of HIMA and PMA (now PhRMA). Dr. Stoll also serves on the University of Connecticut School of Pharmacy Advisory Board. The nominations committee considered Dr. Stoll's experience and qualifications in both pharmaceuticals and medical devices and equipment in addition to his relevant executive management experience. as well as, the overall composition of the Board, in making the determination that Dr. Stoll should serve as a director of Delcath.

*Dr. Marco Taglietti, M.D.* was appointed as a Director in December 2014. Dr. Taglietti serves as CEO and on the Board of Directors of NASDAQ-listed SCYNEXIS, Inc., a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives. Prior to its acquisition in February 2014, Dr. Taglietti served as Executive Vice President, Research and Development, and Chief Medical Officer of Forest Laboratories. He also served as President of the Forest Research Institute. Prior to

joining Forest Labs in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel after 12 years at Schering-Plough Corporation where he last held the position of Vice President, Worldwide Clinical Research for Anti-Infectives, Oncology, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. He received his medical degree and board certifications from the University of Pavia in Italy. The Nominating Committee considered Dr. Taglietti’s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Dr. Taglietti should serve as director of Delcath.

Simon Pedder resigned as a member of the Board of Directors of the Company effective April 10, 2019. Mr. Pedder’s decision to resign was not the result of any disagreement with the Company on any matter relating to its operations, policies or practices.

In addition, information concerning Jennifer K. Simpson, one of our Directors and our President and Chief Executive Officer, is provided under “— Information About Our Executive Officers”

**Information About our Executive Officers**

The following table provides information concerning the current executive officers of Delcath:

<u>Name</u>	<u>Age</u>	<u>Office Currently Held</u>
Jennifer K. Simpson	50	President and Chief Executive Officer
Barbra C. Keck	41	Chief Financial Officer and Secretary
John Purpura	57	Executive Vice President, Global Head of Operations

The following is a brief description of the business experience of our executive officers:

*Jennifer K. Simpson* was appointed as a Director in October 2015. Dr. Simpson joined Delcath as Executive Vice President, Global Marketing in March 2012 and was promoted to Executive Vice President, Global Head of Business Operations in April 2013 and Interim Co-President and Co-Chief Executive Officer, Executive Vice President, Global Head of Business Operations in September 2013. In September 2014, Dr. Simpson was named Interim President and Chief Executive Officer and named President and Chief Executive Officer in October 2015. From May 2011 to March 2012, Dr. Simpson served as the Vice President, Global Marketing, Oncology Brand Lead at ImClone Systems, Inc. (a wholly owned subsidiary of Eli Lilly and Company), where she was responsible for all product commercialization activities and launch preparation for one of the late-stage assets. From June 2009 to May 2011, Dr. Simpson served as the Vice President, Product Champion and from 2008 to 2009 as the Associate Vice President, Product Champion for ImClone’s product Ramucirumab. From 2006 to 2008, Dr. Simpson served as Product Director, Oncology Therapeutics Marketing at Ortho Biotech (now Janssen Biotech), a Pennsylvania-based biotech company that focuses on innovative solutions in immunology, oncology and nephrology. Earlier in her career, Dr. Simpson spent over a decade as a hematology/oncology nurse practitioner and educator. Dr. Simpson earned a Ph.D. in Epidemiology from the University of Pittsburgh, an M.S. in Nursing from the University of Rochester, and a B.S. in Nursing from the State University of New York at Buffalo.

*Barbra C. Keck* joined Delcath as Controller in January 2009, was promoted to Vice President in October 2009, to Senior Vice President in March 2015 and to Chief Financial Officer in February 2017. Prior to joining Delcath, she was an audit assistant with Deloitte & Touche, LLP from August 2008 to December 2008. From June 2006 to August 2008, Ms. Keck was the Assistant to the Vice President and Dean of Baruch College, Zicklin School of Business, and from September 2005 to May 2006 she was the Donor Relations and Communications Manager for Young Audiences New York. From 2002 to 2005, Ms. Keck was the Manager, UD Arts Series at the University of Dayton, where she also served as the Manager, Arts and Cultural Events from 1999 to 2002. Between those positions, from 2002 to 2003, she was the Director of Teacher Programs at the Muse Machine. Ms. Keck served as the General Manager of Dayton Bach Society and the Manager of UD Arts Series from 1999 to 2002. She earned her M.B.A. in Accountancy from Baruch College and Bachelor of Music in Music Education from the University of Dayton.

*John Purpura* joined Delcath as Executive Vice President, Regulatory Affairs and Quality Assurance in November 2009 and was promoted to Executive Vice President, Global Head of Operations on July 19, 2016. Prior to joining Delcath, he was with Bracco Diagnostics (formerly E-Z-EM, Inc.) as Vice President and then Executive Director of International Regulatory Affairs from 2007 to 2008 and Head of Regulatory Affairs for North America and Latin America from 2008 to 2009. Prior to E-Z-EM, Inc., Mr. Purpura had an 11-year career with Sanofi-Aventis, ultimately serving as Associate Vice President for Regulatory CMC from 2005 to 2007. From 1985 to 1995, he had various quality and regulatory management roles with Bolar Pharmaceuticals, Luitpold Pharmaceuticals and Eon Labs Manufacturing. He earned his M.S. in Management & Policy and B.S. degrees in Chemistry and Biology at the State University of New York at Stony Brook.



**Board of Directors.** We have currently have four directors serving on the Board of Directors. The Board of Directors oversees the business affairs of the Company and monitors the performance of management. In accordance with our corporate governance principles, our Board does not involve itself in day-to-day operations. The directors keep themselves informed through discussions with the Chairman of the Board, Roger G. Stoll, Jennifer K. Simpson, in her capacity as Director and Chief Executive Officer, or CEO, and other key executives, and by reading the reports and other materials that management sends them and by participating in Board and committee meetings. Our directors hold office until their successors have been elected and qualified unless the director resigns or is removed or by reason of death or other cause is unable to serve in the capacity of director.

**Board Independence.** The Board has determined that three of our four directors (each of Roger Stoll, William D. Rueckert and Marco Taglietti) are “independent” directors within the meaning of the NASDAQ listing rules.

**Attendance.** The Board of Directors met 12 times in 2018 (including regularly scheduled and special meetings). During 2018, each director attended at least 75% of the aggregate of: (i) the total number of meetings of the Board (held during the period for which he or she served as a director) and (ii) the total number of meetings held by all committees of the Board of Directors on which he or she served (held during the period that he or she served). It is Delcath’s policy that, absent unusual or unforeseen circumstances, all directors are expected to attend annual meetings of stockholders.

**Board Leadership Structure.** Roger G. Stoll, Ph.D. was appointed Executive Chairman effective September 2014 and designated Chairman in connection with the appointment of Dr. Simpson as director effective October 2015. Dr. Stoll has been a member of the Board of Directors since 2008.

It is our policy to separate the Chairman and Chief Executive Officer roles. We believe this structure is appropriate for Delcath because it allows our President and CEO to concentrate on Delcath’s day-to-day operations, while providing for effective oversight by the Chairman, who is involved in strategic and key matters, such as business strategy, major transactions and the broader business of Delcath. For a company like Delcath that is focused on the development, approval and commercialization of a specialized product in an extremely technical, highly regulated and intensely competitive industry, we believe our President and CEO is in the best position to lead our management team, in part because of the depth of her experience in conducting clinical trials in oncology, and to respond to the current pressures and needs of a company in the stage of growth and development of Delcath, with assistance from our Chairman who also focuses the Board’s attention on the broader issues of corporate business strategy and corporate governance. We believe that splitting the roles between Chairman, on the one hand, and President and CEO, on the other hand, minimizes any potential conflicts that may result from combining the roles of CEO, President and Chairman, and maximizes the effectiveness of our management and governance processes to the benefit of our stockholders. Our President and CEO and Chairman regularly consult with each other as part of this structure.

**Board’s Role in Risk Oversight.** The Board as a whole is responsible for risk oversight, with reviews in certain areas being conducted by the relevant Board committees. Each of the Board’s committees oversees the management of risks associated with their respective areas of responsibility. In performing this oversight function, the committees are assisted by management which provides visibility about the identification, assessment and monitoring of potential risks and management’s strategy to mitigate such risks. Key members of management responsible for a particular area report directly to the Board committee charged with oversight of the associated function and, if the circumstances require, the whole Board. The Board committees review various risk exposures with the full Board and otherwise keep the full Board abreast of the committees’ risk oversight activities throughout the year, as necessary or appropriate.

**Risk Assessment of Compensation Programs.** Our Compensation and Stock Option Committee annually evaluates whether our compensation programs encourage excessive risk-taking by employees at the expense of long-term Company value. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in the Company’s stock incentive plans and the Compensation Committee’s role in the consideration and approval of certain awards, the Compensation and Stock Option Committee does not believe that our compensation programs encourage excessive or inappropriate risk-taking, motivate imprudent risk-taking or create risks that are reasonably likely to have a material adverse effect on the Company.

**Board Committees.** Our Board has three standing committees: an Audit Committee, a Compensation and Stock Option Committee and a Nominating and Corporate Governance Committee. No individual director is the chairman of more than one committee.

**Audit Committee.** The Audit Committee provides assistance to the Board in fulfilling its oversight responsibilities with respect to the Company's financial statements, the Company's system of internal accounting and financial controls and the independent audit of the Company's financial statements. Functions of the Audit Committee include:

- the selection, evaluation and, where appropriate, replacement of our outside auditors;
- an annual review and evaluation of the qualifications, performance and independence of our outside auditors;
- the approval of all auditing services and permitted non-audit services provided by our outside auditors;
- the review of the adequacy and effectiveness of our accounting and internal controls over financial reporting; and
- the review and discussion with management and with our outside auditors of the Company's financial statements to be filed with the Securities and Exchange Commission (the "SEC").

The Board has determined that each member of the Audit Committee, William D. Rueckert (Chair), Marco Taglietti and Roger Stoll qualifies as an "audit committee financial expert" as defined by SEC rules. During 2018, the Audit Committee met five times. Each member of the Audit Committee is "independent" within the meaning of the NASDAQ listing rules and otherwise meets the financial statement proficiency requirements of the NASDAQ listing rules. The Audit Committee has a written charter, which is available on our website; go to [www.delcath.com](http://www.delcath.com), click on "Investors," then "Corporate Governance."

**Compensation and Stock Option Committee.** The Compensation and Stock Option Committee (the "Compensation Committee") assists the Board of Directors in the discharge of the Board's responsibilities with respect to the compensation of Delcath's directors, executive officers, and other key employees and consultants. The Compensation Committee establishes our overall compensation philosophy and is authorized to approve the compensation payable to our executive officers, including our named executive officers, and other key employees, including all perquisites, equity incentive awards, cash bonuses, and severance packages. The Compensation Committee also administers certain of the Company's employee benefit plans, including its equity incentive plans, and is responsible for assessing the independence of compensation consultants and legal advisors. The Compensation Committee has concluded that each of Wexler, Burkhart, Hirschberg & Unger, LLP, outside legal counsel to the Compensation Committee and the Company, as well as Pearl Meyer & Partners, compensation consultant to the Compensation Committee, qualified as independent. The Compensation Committee exercises sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements. The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert, and Roger Stoll, each of whom is "independent" within the meaning of NASDAQ listing rules. During 2018, the Compensation and Stock Option Committee met one time. The Compensation and Stock Option Committee has a written charter, which is available on our website; go to [www.delcath.com](http://www.delcath.com), click on "Investors," then "Corporate Governance."

**Nominating and Corporate Governance Committee.** The Nominating and Corporate Governance Committee (the "Nominating Committee") is responsible for identifying individuals qualified to become Board members, and recommends to the Board the director nominees to be proposed by the Board for election by the stockholders (as well as any director nominees to be appointed by the Board to fill interim vacancies). The Nominating Committee also recommends the directors to be selected for membership on each Board committee.

The Nominating Committee is also responsible for developing and recommending to the Board appropriate corporate governance guidelines and policies, and for leading the Board in its annual review of the Board's performance.

The current members of the Nominating Committee are Roger Stoll (Chairman), William D. Rueckert and Marco Taglietti, each of whom is "independent," within the meaning of NASDAQ listing rules. During 2018, the Nominating Committee met one time. The Nominating Committee has a written charter, which is available on our website; go to [www.delcath.com](http://www.delcath.com), click on "Investors," then "Corporate Governance."

The Nominating Committee, with, when it deems it necessary, the assistance of a third-party search firm, identifies candidates for director nominees. In considering candidates for the Board, the Nominating Committee considers each candidate's credentials as a whole, including, but not necessarily limited to, outstanding achievement in a candidate's personal career, broad and relevant experience, integrity, sound and independent judgment, experience and knowledge of the business environment and markets in which the Company operates, business acumen, and willingness and ability to devote adequate time to Board duties. The Nominating Committee considers the diversity of its members in the context of the Board as a whole, including the personal characteristics, experience and background of directors and nominees to facilitate Board deliberations that reflect a broad range of perspectives.

**Recommendations by Stockholders of Director Nominees.** The Nominating Committee will consider any recommendation by a stockholder of a candidate for nomination as a director. If a stockholder wants to recommend a director candidate for consideration by the Nominating Committee, the stockholder should submit the name of the proposed nominee, together with the reasons why the stockholder believes the election of the candidate would be beneficial to the Company and its stockholders and the information about the nominee that would be required in a proxy statement requesting proxies to vote in favor of the candidate. The stockholder's submission must be accompanied by the written consent of the proposed nominee to being nominated by the Board and the candidate's agreement to serve if nominated and elected. Any such submission should be directed to the Nominating Committee at Delcath's principal office, 1633 Broadway, Suite 22C, New York, New York 10019. If a stockholder intends to nominate a person for election to the Board of Directors at an annual meeting, the stockholder must provide Delcath with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in Delcath's proxy statement for such meeting and must otherwise comply with our amended and restated certificate of incorporation. Copies of any recommendation received in accordance with these procedures will be distributed to each member of the Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

**Stockholder Communications with the Board of Directors.** Any stockholder wishing to communicate with the Board or with any specified director should address his or her communication to the Board of Directors or to the particular director(s) in care of the Corporate Secretary, Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019. All such written communication, other than items determined by our legal counsel to be inappropriate for submission to the intended recipient(s), will be submitted to the Board or to the particular director(s). Any stockholder communication not so delivered, will be made available upon request to any director. Examples of stockholder communications that would be considered inappropriate for submission include, without limitation, customer complaints, business solicitations, product promotions, job inquiries, junk mail and mass mailings, as well as material that is unduly hostile, threatening, illegal or similarly unsuitable.

**Code of Ethics.** 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 website at <http://delcath.com/investors/governance>. We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer or principal accounting officer and persons performing similar functions on our website.

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

## **REPORT OF THE AUDIT COMMITTEE**

The Audit Committee reviewed and discussed the Company's audited financial statements for the fiscal year ended December 31, 2018, with management and Marcum LLP, the Company's independent registered public accounting firm for the fiscal year ended December 31, 2018. The Audit Committee also discussed with Marcum LLP the matters required to be discussed by the Statement on Auditing Standards No. 16, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T regarding "Communication with Audit Committees." The Audit Committee has received and reviewed the written disclosures and the letter from Marcum LLP required by applicable requirements of the Public Company Accounting Oversight Board regarding Marcum LLP's communications with the Audit Committee concerning independence, and has discussed with Marcum LLP its independence from the Company.

Based on the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, for filing with the SEC.

Submitted by the Audit Committee of the Board of Directors,  
William Rueckert (Chair)  
June 14, 2019

## SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who are beneficial owners of more than 10% of our common stock to file with the SEC reports of holdings and changes in beneficial ownership of Delcath's equity securities. Based on a review of copies of reports furnished to Delcath or written representations that no reports were required, with the exception of one late filed Form 4 for each of Jennifer Simpson, Barbra Keck, John Purpura, Roger Stoll and William Rueckert, we believe that all reports were timely filed in 2018.

### Item 11. Executive Compensation.

Our Compensation Committee is responsible for formulating and establishing our overall compensation philosophy with respect to our executive officers. The Company believes that a strong executive management team comprised of talented individuals in key positions at the Company is critical to the development and growth of our business and to increasing stockholder value. Accordingly, a key objective of executive compensation is to attract and retain talented and experienced individuals, while motivating them to perform and make decisions consistent with the Company's business objectives, goals and culture. We emphasize pay-for-performance by linking executive compensation to Company performance. For each executive, the amount of pay that is actually realized is primarily driven by the Company's performance and each executive's contribution to that performance.

Our Compensation Committee considers the input it receives from our stockholders when designing and evaluating our executive compensation practices. *Compensation Components.* The three primary components of executive compensation are base salary, annual incentive cash awards and long-term equity incentive awards:

- *Base Salary.* We pay our executive officers a base salary, which our Compensation Committee reviews and determines annually. Base salaries are used to compensate our executive officers for performing the core responsibilities of their positions and to provide them with a level of security with respect to a portion of their total compensation. Base salaries are set in part based on the executive's unique skills, experience and expected contribution to the Company, as well as individual performance, including the impact of such performance on our business results, and the period of the executive's performance. Decisions regarding base salary increases take into account the executive's current base salary, third-party benchmark and survey data, and the salary compensation paid to executive officers within and outside the Company, as well as the Company's overall performance, its ability to afford such increases, its success in achieving its operational and strategic goals and objectives, and the executive officer's contribution to Company performance.
- *Annual Incentive Cash Awards.* Annual incentive compensation is intended to establish a direct correlation between annual cash awards and the performance of the Company. The Company's Annual Incentive Plan ("AIP") is an annual incentive cash bonus plan designed to align the interests of participants with the interests of the Company and its stockholders. The AIP is designed to strengthen the link between a participant's pay and his or her overall performance and the Company's performance, focus participants on critical individual and corporate objectives, offer a competitive cash incentive, and encourage and reward performance and competencies critical to the Company's success.
- *Long-Term Incentive Compensation.* In addition to using base salaries and annual incentive cash bonuses, which our Compensation Committee views as short-term compensation, a portion of our executive compensation is in the form of long-term equity compensation. Our Long-Term Incentive Plan ("LTIP") is an annual equity-based incentive plan designed to align participants' interests with those of the Company and its stockholders by rewarding participants for their contributions to the long-term success of the Company. The LTIP is designed to incentivize Company leaders to focus on the long-term performance of the Company, offer participants competitive, market-based long-term incentive award opportunities, and strengthen the link between a participant's compensation and his or her overall performance and the Company's overall long-term performance. We believe the LTIP assists us in achieving an appropriate balance between short- and long-term executive compensation.

*Base Salary.* The following table summarizes the amount of base salary and year-over-year increase for each of our named executive officers for 2017 and 2018:

<b>Executive</b>	<b>Hire Date</b>	<b>2016 Base Salary</b>	<b>Percent Increase in 2017</b>	<b>2017 Base Salary</b>	<b>Percent Increase in 2018</b>	<b>2018 Base Salary</b>
Jennifer K. Simpson, Ph.D.	3/23/2012	\$ 439,810	3.0%	\$ 453,004	3.0%	\$ 466,594
Barbra C. Keck, M.B.A.	1/5/2009	\$ 247,200	21.4%	\$ 300,000	8.0%	\$ 324,000
John Purpura, M.S.	11/16/2009	\$ 307,000	3.0%	\$ 316,210	5.9%	\$ 335,000

*Annual Incentive Plan.* Under the AIP, annual incentive target award opportunities are expressed as a percentage of a participant's actual base salary for the performance year, beginning January 1. The following table sets forth, for each executive, the applicable target bonus percentage of base salary to which each executive could have been entitled. Given the Company's current position, no annual bonus was awarded or paid to any named executive officer for 2018.

<b>Executive</b>	<b>Target Bonus Expressed as % of Base Salary</b>	<b>Dollars (\$)</b>	<b>Actual Payout as % of Base Salary</b>	<b>Dollars (\$)</b>
Jennifer K. Simpson, Ph.D.	50.0%	\$ 233,297	0.0%	\$ —
Barbra C. Keck, M.B.A.	45.0%	\$ 145,800	0.0%	\$ —
John Purpura, M.S.	45.0%	\$ 150,750	0.0%	\$ —

For 2018, AIP goals were based entirely on Company performance to focus all the executives on the same critical challenges facing the Company. Company performance in 2018 has been measured based upon achievement of objectives in the following areas: (1) Clinical Trials; (2) Capital; and (3) Sales. While certain performance goals were met in 2018, the Board determined that no annual bonus should be granted to our named executive officers due to the Company's current position and challenges.

*Long Term Incentive Plan.* Grants under the LTIP are typically comprised of a mix of restricted stock and stock option awards granted in the first quarter of each year with the number of shares subject to the awards designed to deliver a competitive value targeted at the mid-market of the executive compensation comparison group. These guidelines are reviewed periodically based on prevailing compensation comparison group levels, however, and the Compensation Committee then uses these guidelines to determine long-term equity incentive awards for our named executive officers based upon a holistic assessment of Company and individual performance for the prior year and its view of the appropriate incentives to best help achieve the Company's business objectives. Our ability to provide awards at the mid-market level has been difficult to do in the past few years due to share availability. Such awards in the past few years have typically been at or below the market 25th percentile.

There were no long-term equity awards to our named executive officers in 2018. Due to the lack of available shares for issuance under the Company's 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2018 which in no way should create any negative inference concerning the Compensation Committee's evaluation of their performance.

## Summary Compensation Table.

The following table sets forth the total compensation awarded to, earned by or paid to: (i) each person who served as a principal executive officer during 2018, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2018. We refer to these individuals as our “named executive officers.”

Name and Position	Year	Salary \$(1)	Bonus \$(2)	Stock Awards \$(3)	Options Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
<b>Jennifer K. Simpson, Ph.D.</b>	2018	\$ 466,594	\$ 75,000	\$ —	\$ —	\$ —	\$ —	\$ 541,594
President and Chief Executive Officer	2017	453,004	147,226	7,476	—	—	—	607,706
<b>Barbra C. Keck, M.B.A.</b>	2018	324,000	50,000	—	—	—	—	374,000
Chief Financial Officer and Secretary	2017	293,400	68,250	4,788	—	—	—	366,438
<b>John Purpura, M.S.</b>	2018	335,000	50,000	—	—	—	—	385,000
Executive Vice President, Global Head of Operations	2017	316,210	92,491	7,140	—	—	—	415,841

- (1) For 2018, Dr. Simpson was paid \$177,102, Ms. Keck was paid \$128,037 and Mr. Purpura was paid \$132,053. The balance of their salaries has been accrued.
- (2) For 2017 and 2018, all bonus amounts have been accrued and not yet paid.
- (3) Due to the lack of available shares for issuance under the Company’s 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2017 or 2018 which in no way should create any negative inference concerning the Compensation Committee’s evaluation of their performance.

## Outstanding Equity Awards at Fiscal Year-End Table—2018.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2018. As a result of the May 2, 2018 reverse stock split, the Company’s 2009 Stock Incentive Plan has no active grants and no further shares available to be granted.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$)
Jennifer K. Simpson, Ph.D.	—	—	—	—	—	—
Barbra C. Keck, M.B.A.	—	—	—	—	—	—
John Purpura, M.S.	—	—	—	—	—	—

## Potential Payments upon Termination or Change of Control.

The following table shows the potential incremental value transfer to each named executive officer under various termination or change-in-control scenarios as of December 31, 2018, the last business day of 2018. Unvested, unexercised stock options and unvested restricted stock awards are valued at the closing market price of the Company's common stock on that date. The actual amounts to be paid out in respect of the named executive officers can only be determined at the time of such named executive officer's actual separation from the Company.

Name	Retirement or Voluntary Termination Without "Good Reason"	Termination for "Cause"	Involuntary Termination (Termination Without Cause, or Termination for Good Reason)	Upon a Change in Control	Death or Disability Termination
Jennifer K. Simpson, Ph.D.	—	—	\$ 726,650	\$ 726,650	—
Barbra C. Keck, M.B.A.	—	—	\$ 530,860	\$ 530,860	—
John Purpura, M.S.	—	—	\$ 518,240	\$ 518,240	—

## Severance Arrangements

The Company has entered into an Executive Security Agreement with each of the named executive officers. The Executive Security Agreements provide for the payment of severance to each of our named executive officers upon a qualifying termination (a termination which is involuntary but not "for cause" or a termination for "good reason" as defined therein) to be paid within 10 days of such event as follows: (i) all base salary owed to the date of the qualifying event, (ii) a one-time lump sum fee equal to the named executive officer's monthly base salary for a term of two years for Jennifer Simpson and 18 months for Barbra Keck and John Purpura, and (iii) COBRA payments should the named executive officer remain on the Company's health benefit plans. The named executive officer would also be entitled to a pro-rata portion of any AIP payment for the fiscal year in which termination of employment occurs due by March 15th of the following year. The term of the Executive Security Agreements continues until terminated by mutual agreement of each named executive officer and the Company.

## Director Compensation—2018

The Compensation Committee reviews and recommends to the Board of Directors appropriate director compensation programs for service as directors, committee chairs, and committee members.

In lieu of per-meeting fees, non-employee directors of the Company are paid an annual retainer of \$43,000 and certain additional annual retainers for chairing or serving as a member of the committees of the Board as follows:

Name	Annual Retainer
Board Service	\$ 43,000
Chair of Audit Committee	\$ 20,000
Member of Audit Committee	\$ 8,000
Chair of Compensation and Stock Option Committee	\$ 12,000
Member of Compensation and Stock Option Committee	\$ 5,000
Chair of Nominating and Corporate Governance Committee	\$ 8,000
Member of Nominating and Corporate Governance Committee	\$ 4,000

Dr. Stoll receives an annual retainer fee as Director and Chairman of the Board of \$68,000. Additionally, we reimburse all non-employee directors for their reasonable out-of-pocket travel expenses incurred in attending meetings of our Board of Directors or any committees of the Board. Due to the lack of shares available for issuance under the Company's 2009 Stock Incentive Plan, the Board of Directors did not grant any equity awards to non-employee directors during 2018 which in no way should create any negative inference concerning the Compensation Committee's evaluation of their performance.

The following table sets forth the compensation awarded to, earned by or paid to each non-employee director who served on our Board of Directors in 2018.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Simon Pedder, Ph.D. (1)	\$ 56,000	\$ —	\$ —	\$ —	\$ 56,000
William D. Rueckert	72,000	—	—	—	72,000
Roger G. Stoll, Ph.D.	84,000	—	—	—	84,000
Marco Taglietti, M.D.	59,000	—	—	—	59,000

- (1) Dr. Pedder resigned as a director effective April 10, 2019.  
(2) No non-employee director was paid his 2018 fees. All amounts have been accrued.

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

The following table contains information regarding the beneficial ownership of our common stock as of June 14, 2019, held by: (i) each of our directors; (ii) each of our named executive officers; (iii) all of our directors and executive officers as a group; and (iv) each person or group known by us to own beneficially more than 5% of the outstanding shares of common stock of the Company. We are not aware of any 5% or more holders of our common stock as of June 14, 2019 except as set forth below. The information set forth in the table below excludes shares issuable upon exercise of outstanding warrants to purchase shares of our common stock held by certain investors that are presently exercisable, subject to limitations on exercisability for more than 4.9% or 9.9% of our outstanding shares of common stock, depending upon the particular investor. Except as indicated in the footnotes below, the address of the persons or groups named below is c/o Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019.

Name of Beneficial Owner	Shares Beneficially Owned Number(1)	Percent
<i>Named Executive Officers and Directors:</i>		
Jennifer K. Simpson, Ph.D.(2)	182,500	*
Barbra C. Keck, M.B.A.(3)	132,500	*
John Purpura, M.S.(4)	130,501	*
William D. Rueckert(5)	57,926	*
Roger G. Stoll, Ph.D.(6)	55,901	*
Marco Taglietti, M.D.(7)	50,001	*
<b>All directors and executive officers as a group (6 people)(8):</b>	<b>609,329</b>	<b>*</b>

\* Less than 1%

- (1) Except as indicated in these footnotes: (i) the persons named in this table have sole voting and investment power with respect to all shares of common stock beneficially owned; (ii) the number of shares beneficially owned by each person as of June 14, 2019, includes any vested and unvested shares of restricted stock and any shares of common stock that such person or group has the right to acquire within 60 days of June 14, 2019, upon the exercise of stock options; and (iii) for each person or group included in the table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the 18,277,807 shares of common stock outstanding on June 14, 2019, plus the number of shares of common stock that such person or group has the right to acquire within 60 days of June 14, 2019.  
(2) Includes 175,000 shares of common stock, which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.  
(3) Includes 125,000 shares of common stock, which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.  
(4) Includes 125,000 shares of common stock, which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.  
(5) Includes 50,000 shares of common stock, which Mr. Rueckert has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.



- (6) Includes 50,000 shares of common stock, which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.
- (7) Includes 50,000 shares of common stock, which Dr. Taglietti has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.
- (8) Includes 50,000 shares of common stock, which certain directors and executive officers have the right to acquire upon exercise of outstanding options exercisable within 60 days of June 14, 2019.

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

**Transactions with Related Persons.** We have adopted a written policy for the review and approval or ratification of transactions between Delcath and Related Parties (as defined below). Under the policy, our Nominating Committee will review the material facts of proposed transactions involving Delcath in which a Related Party will have a direct or indirect material interest. The Nominating Committee will either approve or disapprove Delcath's entry into the transaction or, if advance approval is not feasible, will consider whether to ratify the transaction. The Nominating Committee may establish guidelines for ongoing transactions with a Related Party, and will review such transactions at least annually. If the aggregate amount of the transaction is expected to be less than \$200,000, such approval or ratification may be made by the Chair of the Committee. In determining whether to approve or ratify a transaction with a Related Party, the Nominating Committee (or Chair) will consider, among other factors, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party and the extent of the Related Party's interest in the transaction.

Certain transactions are deemed pre-approved under the policy, including compensation of executive officers and directors (except that employment of an immediate family member of an executive officer requires specific approval), and transactions with a company at which the Related Party's only relationship is as a non-officer employee, director, or less than 10% owner if the aggregate amount involved does not exceed 2% of such company's total annual revenues (or, in the case of charitable contributions by Delcath, 2% of the charity's total annual receipts). Pre-approval is not required if the amount involved in the transaction is not expected to exceed \$120,000 in any calendar year.

For purposes of the policy, a Related Party is generally anyone who since the beginning of the last full fiscal year is or was an executive officer, director or director nominee, owner of more than 5% of the common stock, or immediate family member of any of such persons.

No Related Party transactions occurred during 2018.

### **Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws**

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two-thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

### ***Staggered Board of Directors***

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

### ***Authorized But Unissued Shares***

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

**Item 14. Accounting Fees and Services.**

The aggregate fees billed by Marcum LLP and Grant Thornton LLP for services rendered as our independent registered public accounting firm during the fiscal years ended December 31, 2018 and 2017, respectively:

	Fiscal Year(1)	
	2018	2017
Audit Fees	\$ 104,063	\$ 576,450
Audit-Related Fees	—	—
Tax Fees	—	—
Total	<u>\$ 104,063</u>	<u>\$ 576,450</u>

- (1) Marcum LLP audited Delcath's annual financial statements for the fiscal year ended December 31, 2018 and Grant Thornton LLP audited Delcath's financial statements for the fiscal year ended December 31, 2017

**Audit Fees.** These are fees for services rendered in connection with the audit of the annual financial statements included in our annual reports on Forms 10-K; the review of the financial statements included in our Quarterly Reports on Forms 10-Q; the audit of our internal control over financial reporting; and for services that are normally provided by an independent auditor in connection with statutory and regulatory filings or engagements.

**Pre-approval Policies: Audit and Non-Audit Services.** The Audit Committee pre-approves all audit services and the terms of such services and permissible non-audit services provided by Delcath's independent registered public accounting firm, prior to its engagement for the provision of such services. The Chair of the Audit Committee has been delegated the authority by the committee to pre-approve interim services by Delcath's independent registered public accounting firm; provided the Chair reports all such pre-approvals to the entire Audit Committee at the next Committee meeting. There were no non-audit services provided to Delcath by our independent registered public accounting firm for 2018 and 2017 that required review by the Audit Committee.

**Item 15. Exhibits and 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, 2018 and 2017
- Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017
- Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017
- Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017
- 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.

## Exhibit Index

Exhibit No.	Description
1.1	<a href="#"><u>Form of Placement Agency Agreement (incorporated by reference to the Exhibit 1.1 to Amendment No. 2 to Registration Statement on Form S-1, filed on January 17, 2018 (Commission File No. 333-220898))</u></a>
1.2	<a href="#"><u>Form of Placement Agency Agreement (incorporated by reference to the Exhibit 1.2 to Amendment No. 2 to Registration Statement on Form S-1, filed on January 17, 2018 (Commission File No. 333-220898))</u></a>
1.3	<a href="#"><u>Form of Placement Agency Agreement (incorporated by reference to the Exhibit 1.3 to Amendment No. 2 to Registration Statement on Form S-1, filed on January 17, 2018 (Commission File No. 333-220898))</u></a>
3.1	<a href="#"><u>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))</u></a>
3.2	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of April 8, 2014 (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))</u></a>
3.3	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133))</u></a>
3.4	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.2 to Company's Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133))</u></a>
3.5	<a href="#"><u>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))</u></a>
3.6	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of June 30, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 3, 2017 (Commission File No. 001-16133))</u></a>
3.7	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 5, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 6, 2017 (Commission File No. 001-16133))</u></a>
3.8	<a href="#"><u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of September 20, 2017 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed September 21, 2017 (Commission File No. 001-16133))</u></a>
3.9	<a href="#"><u>Amendment to Amended and Restated Certificate of Incorporation of the Company, effective as of April 21, 2018 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed April 26, 2018 (Commission File No. 001-16133))</u></a>
3.10	** <a href="#"><u>Amendment to Amended and Restated Certificate of Incorporation of the Company, effective as of April 21, 2018</u></a>
3.11	<a href="#"><u>Certificate of Designation of Series D Preferred Stock of the Company effective November 5, 2018 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 7, 2018 (Commission File No. 001-16133))</u></a>
4.1	<a href="#"><u>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))</u></a>
4.2	<a href="#"><u>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)</u></a>
4.3	<a href="#"><u>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))</u></a>

Exhibit No.	Description
4.4	<a href="#"><u>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))</u></a> ;
4.5	<a href="#"><u>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))</u></a> ;
10.1	* <a href="#"><u>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))</u></a> ;
10.2	<a href="#"><u>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))</u></a> ;
10.3	<a href="#"><u>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))</u></a> ;
10.4	<a href="#"><u>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))</u></a> ;
10.5	<a href="#"><u>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))</u></a> ;
10.6	† <a href="#"><u>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))</u></a> ;
10.7	<a href="#"><u>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))</u></a> ;
10.8	<a href="#"><u>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))</u></a> ;
10.9	<a href="#"><u>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))</u></a> ;
10.10	<a href="#"><u>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))</u></a> ;
10.11	<a href="#"><u>Form of Warrant Repurchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 3, 2017 (Commission File No. 001-16133))</u></a> ;
10.12	<a href="#"><u>Exchange Agreement dated July 2, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 2, 2017 (Commission File No. 001-16133))</u></a> ;
10.13	<a href="#"><u>Securities Purchase Agreement dated July 5, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 6, 2017 (Commission File No. 001-16133))</u></a> ;
10.14	<a href="#"><u>Form of Leak-Out Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 2, 2017 (Commission File No. 001-16133))</u></a> ;
10.15	<a href="#"><u>Amended and Restated Securities Purchase Agreement dated July 5, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on July 12, 2017 (Commission File No. 001-16133))</u></a> ;
10.16	<a href="#"><u>Form of Restructuring Agreement and Warrant (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 28, 2017 (Commission File No. 001-16133))</u></a> ;
10.17	<a href="#"><u>Securities Purchase Agreement dated September 19, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2017 (Commission File No. 001-16133))</u></a> ;
10.18	<a href="#"><u>Amendment No. 1 to Restructuring Agreement dated October 10, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 11, 2017 (Commission File No. 001-16133))</u></a> ;

<b>Exhibit No.</b>	<b>Description</b>
10.19	<a href="#"><u>Exchange Agreement, dated November 15, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 16, 2017 (Commission File No. 001-16133))</u></a>
10.20	<a href="#"><u>Form of Exchange Note (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 16, 2017 (Commission File No. 001-16133))</u></a>
10.21	<a href="#"><u>Form of Exchange Warrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 16, 2017 (Commission File No. 001-16133))</u></a>
10.22	<a href="#"><u>Exchange Agreement, dated December 28, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 29, 2017 (Commission File No. 001-16133))</u></a>
10.23	<a href="#"><u>Form of Leak-Out Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 29, 2017 (Commission File No. 001-16133))</u></a>
10.24	* <a href="#"><u>Executive Agreement between the Company and Jennifer Simpson (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2018 (Commission File No. 001-16133))</u></a>
10.25	* <a href="#"><u>Executive Agreement between the Company and Barbra Keck (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 26, 2018 (Commission File No. 001-16133))</u></a>
10.26	* <a href="#"><u>Executive Agreement between the Company and John Purpura (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on March 26, 2018 (Commission File No. 001-16133))</u></a>
10.27	<a href="#"><u>Securities Purchase Agreement dated as of June 4, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 8, 2018 (Commission File No. 001-16133))</u></a>
10.28	<a href="#"><u>First Amendment to Securities Purchase Agreement dated as of July 20, 2018 to Securities Purchase Agreement dated as of June 4, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2018 (Commission File No. 001-16133))</u></a>
10.29	<a href="#"><u>First Amendment to Warrants to Purchase Common Stock dated July 20, 2018 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2018 (Commission File No. 001-16133))</u></a>
10.30	<a href="#"><u>Form of Securities Purchase Agreement dated August 31, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.31	<a href="#"><u>Form of Backstop Commitment Purchase Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.32	<a href="#"><u>Form of 8% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.33	<a href="#"><u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.34	<a href="#"><u>Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.35	<a href="#"><u>Form of First Amendment to 8% Senior Secured Convertible Promissory Notes issued June 4, 2018 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.36	<a href="#"><u>Form of Second Amendment to Warrants to Purchase Common Stock issued June 4, 2018 and July 20, 2018 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on September 7, 2018 (Commission File No. 001-16133))</u></a>
10.37	<a href="#"><u>Form of Stock Purchase Agreement dated as of November 6, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 7, 2018 (Commission File No. 001-16133))</u></a>
10.38	†** <a href="#"><u>License, Supply and Marketing Agreement for CHEMOSAT® dated as of December 10, 2018 between the Company and medac Gesellschaft für klinische Spezialpräparate mbH</u></a>

<b>Exhibit No.</b>	<b>Description</b>
10.39	** <a href="#">Form of Exchange Agreement dated December 2018</a>
10.40	** <a href="#">Form of Leak-Out Agreement dated December 2018</a>
10.41	* <a href="#">2019 Equity Incentive Plan (incorporated by reference to Exhibit 4.01 to the Company's Current Report on Form 8-K filed on February 7, 2019 (Commission File No. 001-16133))</a>
10.42	** <a href="#">Global Settlement Agreement dated as of April 18, 2019 by and among the Company, Iroquois Capital Investment Group, LLC, Iroquois Master Fund Ltd. and FirstFire Global Opportunities Fund LLC</a>
10.43	** <a href="#">Securities Purchase Agreement dated as of April 19, 2019</a>
10.44	** <a href="#">Securities Purchase Agreement dated as of April 26, 2019</a>
10.45	** <a href="#">Securities Purchase Agreement dated as of May 9, 2019</a>
10.46	** <a href="#">Securities Purchase Agreement dated as of May 23, 2019</a>
10.47	** <a href="#">Note Purchase Agreement dated as of June 6, 2019 by and among Delcath Systems, Inc., Rosalind Master Fund LP and Rosalind Opportunities Fund I</a>
10.48	** <a href="#">Form of 8% Secured Promissory Note Due June 6, 2021</a>
31.1	** <a href="#">Certification by Principal executive officer Pursuant to Rule 13a 14.</a>
31.2	** <a href="#">Certification by Principal financial officer Pursuant to Rule 13a 14.</a>
32.1	** <a href="#">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.</a>
32.2	** <a href="#">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.</a>
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 omitted.

\* Indicates management contract or compensatory plan or arrangement.

\*\* Filed herewith.

## 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: June 14, 2019

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jennifer K. Simpson</u> Jennifer K. Simpson	President and Chief Executive Officer (Principal Executive Officer)	June 14, 2019
<u>/s/ Barbra C. Keck</u> Barbra C. Keck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 14, 2019
<u>/s/ Roger G. Stoll, Ph.D.</u> Roger G. Stoll, Ph.D.	Chairman of the Board	June 14, 2019
<u>/s/ William Rueckert</u> William Rueckert	Director	June 14, 2019
<u>/s/ Marco Taglietti</u> Marco Taglietti	Director	June 14, 2019



## Amendments to Amended and Restated Certificate of Incorporation to Effectuate Reverse Stock Split

Pursuant to Section 242 of the General  
Corporation Law of the State of Delaware

DELCATH SYSTEMS, INC., a Delaware corporation (hereinafter called the "Corporation"), does hereby certify as follows:

FIRST: Upon the filing and effectiveness (the "Effective Time") pursuant to the General Corporation Law of the State of Delaware (the "DGCL") of this Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Corporation, the Corporation's Amended and Restated Certificate of Incorporation shall be amended by adding the following paragraph at the end of Article FOURTH:

each 500 shares of the Corporation's common stock, par value \$0.01 per share ("Common Stock"), issued and outstanding or held by the Corporation in treasury stock immediately prior to the Effective Time shall automatically be combined into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof, subject to the treatment of fractional interests as described below. Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the reverse stock split. Stockholders of record who otherwise would be entitled to receive fractional shares, will be entitled to rounding up of their fractional share to the nearest whole share. No stockholders will receive cash in lieu of fractional shares. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates") shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the adjustment for fractional shares as described above.

SECOND: The foregoing amendment was duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

THIRD: This Certificate of Amendment shall become effective as of April 21, 2018 at 4:30 PM, New York City time.

IN WITNESS WHEREOF, DELCATH SYSTEMS, INC., has caused this certificate to be duly executed in its corporate name this 17th Day of April, 2018.

DELCATH SYSTEMS, INC.

/s/ Barbra Keck

\_\_\_\_\_  
Barbra Keck

CFO

**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM  
THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD  
BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

License, Supply and Marketing Agreement  
Chemosat®

This License, Supply and Agreement is made as of December 10th, 2018 (hereinafter referred to as "EFFECTIVE DATE") by and

between

Delcath Systems, Ltd.,  
a company duly organised and existing under the laws of Ireland, having its registered office at Unit 19,  
Mervue Business Park, Mervue, Galway  
(VAT No. IE9795453G)

- hereinafter referred to as "Delcath"-

and

medac Gesellschaft für klinische Spezialpräparate mbH,  
a company duly organised and existing under the laws of Germany,  
having its registered office at Theaterstrasse 6, 22880 Wedel, Germany  
(VAT No. DE 118579535)

- hereinafter referred to as "medac"-

hereinafter individually and collectively referred to respectively as "a Party" and "the Parties"

WHEREAS the Parties are established pharmaceutical companies;

WHEREAS Delcath has developed the medical device Delcath Hepatic CHEMOSAT® Delivery System for the application of Melphalan and has obtained CE mark approval thereof;

WHEREAS medac is interested in receiving a license to use the EC certificate and its underlying KNOW-HOW in order to market and sell the PRODUCT in the TERRITORY, and whereas medac is interested in being supplied by Delcath with the medical device for this purpose. Delcath is willing to grant a respective license and to supply the medical device to medac under the terms and conditions set forth in this Agreement;

WHEREAS medac hereby appoints Delcath as its exclusive supplier of the PRODUCT in the TERRITORY;

NOW, THEREFORE, in consideration of the mutual covenants and the premises contained herein, the Parties hereto enter into this License, Supply and Marketing Agreement (the "Agreement") as follows:

## 1. Definitions

For the purposes of this Agreement, each word or expression set out in capital letters in this Agreement and all grammatical variations of such word or expression shall, when capitalized in the manner shown in this Article and used in this Agreement, have the meaning correspondingly assigned to such word or expression in this Article. When not capitalized in the manner shown in this Article and used in this Agreement, such word or expression shall have its ordinary meaning:

- 1.1. "AFFILIATE" shall mean with respect to either Party, any person, corporation, company, partnership, joint venture, firm or other entity which is controlled by, controls or is under direct or indirect common control with such Party. For the purposes of this definition "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors, managing directors and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct management and policies of such non-corporate entities.
- 1.2. "APPLICABLE LAWS" shall mean all laws, guidelines, directives, ordinances, rules and regulations applicable to the manufacture of the PRODUCT and the obligations of either Party, as the context requires under this Agreement, including, without limitation and if applicable, (i) all applicable federal, state and local laws and regulations; (ii) the EU Commission Directive and regulations on the Community code relating to medicinal products for human use; (iii) the EU GMPs; and (iv) any other requirements by any other Regulatory Authority, government or governmental agency.
- 1.3. "CONFIDENTIAL INFORMATION" shall mean all documents, methods, technical KNOW-HOW and all other information that is non-public, confidential and proprietary in nature irrespective of its form (including but not limited to oral, written, printed form or forms of electronic data) disclosed by one Party to the other or any of its directors, officers, employees, agents, consultants or representatives relating to the business of the disclosing Party.
- 1.4. "EX FACTORY PRICE" shall mean the selling price in the various countries, exclusive of taxes and before subtraction of the deductions defined in Schedule 1 of this Agreement. EX-FACTORY PRICE is referred to as the EXF.
- 1.5. "INTELLECTUAL PROPERTY" shall mean patents, designs (registered or not), utility models including applications for any of the foregoing, copyright, rights in KNOW-HOW, brand / trademark, trade or business names trade secrets, and other similar rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world whether registrable or not and any licenses of any of the foregoing.

- 1.6. "INTELLECTUAL PROPERTY OF DELCATH" shall mean any and all INTELLECTUAL PROPERTY relating to the manufacture of the PRODUCT generally, that is; (i) owned by or licensed to Delcath or Delcath's AFFILIATES or Delcath's Subcontractor at the Effective Date; and (ii) developed, filed or acquired by, or licensed to, Delcath or Delcath's AFFILIATES or Subcontractor after the Effective Date of this Agreement.
- 1.7. "KNOW-HOW" shall mean any and all techniques, data and information in the control of Delcath as of the date of this agreement that are necessary or useful to the development, manufacture or commercialization of the PRODUCT, including, but not limited to inventions and intellectual property rights (if any) pertaining thereto, discoveries, practices, processes, procedures, formulae, methods, knowledge, skill, trade secrets, experience, test data, data, records and information derived from development, adverse reactions, analytical and quality control data, including data included in or necessary or useful for obtaining regulatory approval.
- 1.8. "IMPROVEMENT" shall mean any further development, enhancements or improvement relating to the PRODUCT and its underlying KNOW-HOW, whether patentable or not.
- 1.9. "MARKETABILITY" shall mean that the PRODUCT can be lawfully distributed within the TERRITORY which includes that the PRODUCT is free of any defects as well as no administrative orders or jurisdiction can hinder the lawful distribution of the PRODUCT.
- 1.10. "NET SALES" shall mean the amount medac invoices to distributors and/or end users (hospitals, clinics, cancer centers, etc.) for the PRODUCT less
- a) cash discounts, returns as well as purchase taxes and VAT, including but not limited to rebates like the German "*Herstellerrabatt/Generikarabatt*" and respective official rebates and tender related rebates;
  - b) credits or allowances granted on account of rejections, returns and invoicing errors; and
  - c) logistic costs.
- 1.11. "PRODUCT" shall mean the medical device Delcath Hepatic CHEMOSAT® Delivery System for the administration of Melphalan including the labelling, packaging and promotional material.
- 1.12. "PRICE" shall have the meaning as set forth in Schedule 1.
- 1.13. "TERRITORY" shall mean the territory of commercialization of the PRODUCT in the following countries: all member states of the European Union, Norway, Iceland, Liechtenstein, Switzerland and United Kingdom.
- TERRITORY can be extended by mutual agreement between the Parties. Financial consideration should take into consideration the amounts already paid by medac under this Agreement.

2. Condition precedent
  - 2.1. As a condition precedent to this contract, medac will visit the premises of Delcath Ltd. which includes the offices and depots in Ireland and the Agreement shall only be set in force if medac approves Delcath Ltd. as a contractual partner.
3. Scope of the Agreement
  - 3.1. Delcath grants to medac an exclusive license for the PRODUCT in the TERRITORY including any trademarks and/or EC-certificates and/or any approvals which might be necessary for lawful marketing of the PRODUCT and use of the underlying KNOW-HOW and INTELLECTUAL PROPERTY OF DELCATH. Delcath furthermore grants medac the rights for the commercialisation of the PRODUCT in the TERRITORY which shall among others include the rights of promotion, sale and distribution. Other than for countries under 12.3, Delcath is not entitled to commercialise the PRODUCT in the TERRITORY and will refrain from any of these measures.
  - 3.2. Delcath shall transfer a copy of all existing EC-certificates and/or approvals as well as of any other documents which might be necessary for lawful marketing of the PRODUCT within thirty (30) calendar days after execution of this Agreement and shall provide medac with each and any update and/or amendment of these documents.
  - 3.3. medac agrees to use any document and/or information as well as INTELLECTUAL PROPERTY OF DELCATH licensed by Delcath in compliance with this Agreement. In particular medac must not market the PRODUCT in- or outside the TERRITORY for other pharmaceuticals than Melphalan.
  - 3.4. Delcath hereby agrees to sell and supply the PRODUCT only and exclusively to medac for the TERRITORY and medac agrees to purchase the PRODUCT exclusively from Delcath.
  - 3.5. All existing INTELLECTUAL PROPERTY OF DELCATH and any IMPROVEMENT made to the PRODUCT and its underlying KNOW-HOW during the Term shall belong to Delcath and will be considered as part of the PRODUCT with no additional milestone or other payments due by medac. Delcath will notify medac as soon as reasonably possible after making any such IMPROVEMENT giving reasonable details of the IMPROVEMENT and provide medac with all necessary information to evaluate the intellectual property situation, if needed. Any IMPROVEMENT of the PRODUCT and respective INTELLECTUAL PROPERTY OF DELCATH shall be automatically included in this Agreement and medac shall be granted a license within the scope of the license granted under 2.1 for this INTELLECTUAL PROPERTY OF DELCATH.

3.6. In the event Delcath desires to grant a license for commercialization of an invention or discovery which does not meet the definition of PRODUCT or IMPROVEMENT in this Agreement, but is marketed or intended to be marketed at least in one of the indications of the PRODUCT, then Delcath shall inform medac of such desire and grant medac an exclusive right of first negotiation to acquire exclusive rights to commercialize this opportunity.

The exclusive negotiation period shall have a duration of ninety (90) days commencing on the date of delivery to medac by Delcath of a notice pursuant to advising medac of the opportunity. After expiration of this period without a definitive agreement effective upon signing between the negotiating parties, Delcath shall be free to negotiate with any other third party, provided however the definitive agreement with the third party shall not contain terms more favourable than those offered to medac.

3.7. The name of the PRODUCT in the TERRITORY shall be Chemosat®. Delcath owns a respective trademark for the medical device in the TERRITORY and will uphold the respective trademark rights at their own costs including in Switzerland, Norway, Lichtenstein, and Iceland

#### 4. Regulatory Affairs

4.1. Delcath is responsible to fully ensure the MARKETABILITY of the PRODUCT within the TERRITORY. In particular Delcath is responsible to obtain and maintain the EC-certificate and similar certificates as required by applicable law to uphold such MARKETABILITY.

4.2. Delcath is responsible that within the TERRITORY the PRODUCT is fully compliant with any APPLICABLE LAWS and provisions. Delcath is in particular aware of the directive regarding medical devices of the European Union (EU directive 2017/745) including UDI requirements as well as of other APPLICABLE LAWS within the TERRITORY such as medical devices laws and as a material obligation ensures full compliance with the PRODUCT with any terms and provisions of these and any other laws.

4.3. Delcath shall bear all the fees which occur for ensuring the MARKETABILITY of the PRODUCT within the TERRITORY including but not exclusively trademark costs, costs for the EC-Certificate and similar certificates.

4.4. The Parties will enter into a separate Quality Assurance Agreement which also describes activities and responsibilities concerning vigilance.

5. Allowance

5.1. In consideration of the rights granted under this Agreement medac shall pay to Delcath [\*] including VAT in the following instalments:

[\*]

Both Parties agree that if any payments under this agreement are subject to withholding tax according to local German tax law, e.g. allowance, royalties, all payments of medac shall be reduced by the applicable local tax rate. The respective tax amount will be paid by medac to the responsible local tax office. After that medac shall provide Delcath with a certificate stating the withheld tax amount which was transferred to the local tax office for the account of Delcath.

The reduced tax rate according to the corresponding double taxation treaty between Germany and Ireland is applicable if Delcath provides medac with a valid certificate of exemption issued by the German federal central tax office (Bundeszentralamt für Steuern) prior to the date the instalments are due. The Parties mutually assure each other all reasonable assistance in order to receive the certificate of exemption.

6. Purchase of the PRODUCT

6.1. Subject to the terms and conditions of this Agreement, medac shall purchase the PRODUCT from Delcath exclusively for [\*] starting with the first commercial supply from Delcath to medac, provided that there is no infringement issue or third party's right at medac's discretion. After the initial term the Parties intend to renew this Agreement for [\*]. They will negotiate this in good faith at least six months in advance of expiry of the initial term.

6.2. Delcath designs and manufactures the PRODUCT including material, packaging, instructions for use and labelling according to the Regulation (EU) 2017/745 on medical devices. Delcath ensures that the PRODUCT fulfills appropriate conformity assessment procedure established for its class as IIb according to Regulation (EU) 2017/745. Delcath is certified according to EN ISO 13485 via the notified body.

6.2.1. The PRODUCT is legally compliant, has a valid EU declaration of conformity, CE marking of conformity, accompanied by the required instruction for use.

6.2.2. Where Delcath as manufacturer of the PRODUCT is not established in the European Union, Delcath ensures that the PRODUCT is placed on the European Union market according to the provisions of Article 11 of the Regulation (EU) 2017/745.

6.2.3. In order to ensure the applicable requirements and responsibilities, Parties enter into a separate Quality Assurance Agreement at the latest before the PRODUCT is placed on the market.

**[\*] Confidential Treatment Requested**

**License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th**

- 6.2.4. The Quality Agreement defines the responsibilities with respect to quality assurance including, but not limited to, the following obligations of Delcath, sole authorized representative and medac:
- carrying out the manufacturing, quality testing and release of the PRODUCT in accordance with the requirements of the Regulation (EU) 2017/745 in a timely and efficient manner;
  - maintaining the certification of the PRODUCT;
  - verifying EU declaration of conformity, carrying out the of the appropriate conformity assessment procedure by authorized representative;
  - regulation concerning qualification, selection, approval, purchase and maintenance of supplier in accordance with the requirements of quality management system.

6.2.5. In case there is divergence between the Quality Agreement and this Agreement regarding quality issues the Quality Agreement shall be decisive. In all other respects this Agreement shall prevail.

7. Forecast / Orders / Terms of delivery

**[\*]**

8. Audits

medac shall have the right to audit the manufacturing site and quality system of Delcath and its AFFILIATES, e.g. Delcath Systems Inc., USA, for the compliance with regulatory requirements for the manufacturing of the PRODUCT. These audits shall be limited to one time a year and shall take place on any business day after arrangement with Delcath and without unnecessary disturbance of operational procedures. Each Party shall bear its own costs, including, but not limited to, personnel and travel costs, itself. In case there is a reasonable indication that Delcath does not comply with this Agreement or other applicable legal regulations related to the manufacturing of the PRODUCT, medac shall always and without any limitation be entitled to audit the facilities of Delcath and AFFILIATES. In such an event and for any activities required to enhance compliance with regulatory requirements the respective costs shall be borne by Delcath. medac will audit the manufacturing site, the EU release site and the quality system of Delcath prior to the execution of this Agreement.

Delcath shall have the auditing right in order to confirm medac's sales reporting. This audit shall be limited to one time a year and shall take place on any business day after arrangement with medac and without unnecessary disturbance of operational procedures. Each Party shall bear its own costs, including but not limited to personnel and travel costs, itself. In case there is a reasonable indication that medac does not comply with this Agreement, the GxP or other applicable legal regulations, Delcath shall always and without any limitation be entitled to audit the facilities of medac. In such an event the respective costs shall be borne by medac.

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**License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th**



9. PRICES and Payment for the Supply of the PRODUCT
  - 9.1. medac shall pay the PRICE for the PRODUCT as stated in Schedule 1.
  - 9.2. Payment of invoices for PRODUCT are due thirty (30) days after receipt of each invoice for PRODUCT.
  - 9.3. All payments shall be made in Euro.
10. Warranty, Defects in quality/quantity, recalls
  - 10.1. Delcath warrants that the PRODUCT is manufactured according to cGMP and that the PRODUCT has full MARKETABILITY in the TERRITORY.
  - 10.2. medac shall be obliged to inspect and examine the quantity and apparent defects of the PRODUCT immediately upon receipt. Should there be any apparent damage to the packaging of the PRODUCT, medac shall draw up a report of defects to be submitted to Delcath, if applicable. In the event that the PRODUCT does not conform to specifications and warranties of this Agreement or do not comply with legal requirements, medac shall inform Delcath within 10 working days after receipt of the PRODUCT of apparent defects in quality or quantity in writing. Failure or delay shall mean acceptance of the delivered PRODUCT and waiver any potential rights medac may have with respect to the delivered PRODUCT.
  - 10.3. Hidden defects shall be announced to Delcath in writing as soon as possible after detection.
  - 10.4. As soon as possible [\*] shall dispose and replace defective PRODUCT.
  - 10.5. If there is a disagreement between the Parties as to the compliance of the PRODUCT with specifications, warranties and legal requirements sample may be sent to an independent laboratory for final evaluation, which shall be binding for both Parties. The independent laboratory shall be selected by both Parties jointly. In case the Parties do not agree upon an independent laboratory, such shall be chosen by the Chamber of Commerce in Hamburg, Germany. If the independent laboratory finds the PRODUCT to conform to the specifications, warranties and legal requirements medac shall bear the costs of the laboratory and the Chamber of Commerce. Otherwise the costs shall be borne by Delcath.

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10.6. If a recall of the PRODUCT from the market is necessary, or if a health authority requires such withdrawal or recall from a Party, the respective Party shall immediately advise the other Party of such necessity or request, and both Parties shall without delay discuss the modalities of such withdrawal or recall. The final decision on a withdrawal or recall in the TERRITORY shall rest with [\*]. To the extent such withdrawal or recall is due to the non-compliance of the PRODUCT with specifications, warranties, cGMP about which medac informed Delcath in accordance with 9.2 or 9.3 and legal requirements and/or an infringement of third party rights.

[\*].

10.7. In the event that a Party recommends initiating a batch recall or that the health authority requires such batch recall, the Parties shall cooperate in good faith to determine the measures that should be taken. The Parties shall immediately commence research in order to determine the cause of the defect in the batch. The Parties will support each other and provide any necessary assistance in the handling of any PRODUCT return, quality complaint, vigilance activities, and recalls or other Field Safety Corrective Actions (responsibilities are further defined in the Quality Agreement).

- In the event of a batch recall in the following situations:
  - o non-observance by Delcath of the APPLICABLE LAWS, the Quality Assurance Agreement, the GMPs, or any other document relevant to the execution of this Agreement; or
  - o defects in the PRODUCT or its design (including defects of components)
  - o defect in the quality control of the PRODUCT,

[\*]

10.8. In an event as listed in Article 10.7, the disposal of the defective batch shall be carried out at [\*]'s expense. The Party carrying out the disposal shall provide the other Party with a certificate of disposal including the following information:

- The reference number of the corresponding batch; and
- The name of the company which carried out the disposal; and
- The quantity of the PRODUCT of which Delcath, or the company it has nominated, has disposed.

10.9. The Parties shall inform each other immediately of any claims with regard to the PRODUCT arising from a third party or health authority and give each other all reasonable support.

**[\*] Confidential Treatment Requested**

**License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th**

11. Responsibilities, Warranties, Indemnity and Liability
- 11.1. Delcath is responsible for maintaining any CE mark as required by national law. Delcath is also responsible to uphold trademark protection for the PRODUCT within the TERRITORY.
- 11.2. Delcath will name medac on the PRODUCT sold under the Agreement as Delcath's exclusive marketing, sales, and distribution partner for the Territory. medac is entitled to apply a respective signature on PRODUCT, packaging and all other material relating to the PRODUCT.
- 11.3. Delcath will identify and transfer all existing customers in the TERRITORY to medac in accordance with Schedule 4.
- 11.4. Delcath will provide all the background information and correspondence with authorities regarding reimbursement in the TERRITORY.
- 11.5. Delcath will supply medac with the PRODUCT from Delcath's own manufacturing facility in the United States through its distribution center in Ireland.
- 11.6. Delcath will be responsible for gaining, maintaining and or renewing import licenses and other regulatory clearances and approvals needed to import the PRODUCT into each country of the TERRITORY.
- 11.7. Delcath will be responsible to prosecute, maintain, enforce and defend INTELLECTUAL PROPERTY OF DELCATH using commercially reasonable efforts.
- 11.8. Delcath warrants and represents to and for the benefit of medac under this Agreement that all PRODUCT supplied by Delcath shall be manufactured, packaged, tested, stored, delivered in accordance with this Agreement, the general and specific manufacturing procedures, the Quality Agreement, the EU GMP, APPLICABLE LAWS and the specifications.
- 11.9. Delcath further warrants and represents to and for the benefit of medac:
- that the PRODUCT has been lawfully assembled by Delcath in compliance with all industry norms and that all related documents disclosed by Delcath to medac will be true, correct and complete and there is no other fact or matter not disclosed to medac under this Agreement, which might reasonably affect medac's willingness to enter into this Agreement;
  - that the PRODUCT is feasible at an industrial level and is of merchantable quality;
  - the PRODUCT and related documents are provided to medac free and clear of all liens, claims and encumbrances.

- 11.10. medac, in its turn, guarantees, warrants and represents to and for the benefit of Delcath under this Agreement full compliance with all APPLICABLE LAWS and regulations in the TERRITORY as regards storage and/or handling and/or promotion and/or distribution and/or marketing of the PRODUCT in the TERRITORY.
- 11.11. medac will be responsible for commercializing, including promoting the sale of, and distributing, the PRODUCT in the TERRITORY and will bear all costs related to the distribution and commercialization of the PRODUCT in the TERRITORY. Medac shall at its own cost employ, train and maintain suitably qualified personnel to ensure the proper fulfilment of all of its obligations in the TERRITORY.
- 11.12. medac will commercialize and distribute the PRODUCT in each country of the TERRITORY where it is commercially reasonable to do so and will commence these activities in a commercially reasonable timeframe. Medac will be responsible for marketing on a regional, local and hospital level in the TERRITORY. To the extent permitted by any APPLICABLE LAWS, the Parties will cooperate with each other with respect to all reimbursement and price negotiations as well as health technology assessments.
- 11.13. medac will provide Delcath with quarterly reports of sales of PRODUCT in the TERRITORY.
- 11.14. Each Party warrants to the other that:
- it is a company duly incorporated, validly existing and in good standing under the law of the country of its incorporation and has the requisite capacity, power and authority to enter into and to perform its obligations under this Agreement;
  - execution, delivery of and the performance by the Party of its obligations under this Agreement shall not:
    - o result in a breach of any provisions of the memorandum or Articles of association of that Party;
    - o result in a breach of, or constitute a default under, any instrument by which the Party is bound including any agreement or arrangement between itself, one of its AFFILIATES and any third party; or
    - o result in a breach of any order, judgment or decree of any court or governmental agency by which the Party is bound; or result in breach by that Party (or any of its employees or agents) of any regulatory requirements.
- 11.15. The warranties provided for in this Article 11 shall be in addition to those implied by law.

- 11.16. Either Party shall defend, indemnify and hold the other Party harmless from and against any third party claim, damage, costs, expenses, injury or loss except indirect losses whatsoever based upon or arising out of any (a) breach of warranties by the former Party and/or (b) any gross negligence or wilful misconduct of the former Party under this Agreement and/or (c) any material breach, non-observance or non-performance by the former Party of its obligations under this Agreement.
- 11.17. To the extent permitted by law, neither Party shall be liable for indirect, punitive, consequential or special damages whatsoever, unless not otherwise expressly agreed in this Agreement.
- 11.18. Nothing in this Agreement shall operate to exclude or restrict either Party's liability for:
- death or personal injury resulting from wilful misconduct;
  - fraud or deceit;
  - any other form of liability which may not be excluded or limited by APPLICABLE LAWS.
- 11.19. In the light of this Article, the Parties agree to take out and keep up to date for the duration of this Agreement and any extensions thereof, an insurance policy financially substantial enough to cover all and any liability incurred by virtue of the said clauses. Each Party agrees that on request by the other Party it shall prove by written records the existence and conditions of such an insurance policy.
- 11.20. The Parties each designate individuals who will participate in a monthly conference call, which can become less frequent as time goes on, to discuss clinical programs, medical information, customer feedback and issues.

Medac appoints the following individuals:

1. [\*] (Vice President Therapeutic Area Oncology)
2. [\*] (Director Therapeutic Area Oncology)
3. [\*](Global Portfolio Manager Oncology)
4. [\*] (Responsible Person for Scientific Information)

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License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th

Delcath appoints the following individuals:

1. **[\*]** CEO, Delcath Systems, Inc.
2. **[\*]** Executive Vice President, Global Head of Operations, Delcath Systems, Inc.
3. **[\*]** Vice President – Medical Affairs, Delcath Systems, Inc.
4. Delcath Systems, Ltd.: within 10 (ten) days after signing of this Agreement Delcath will appoint a Representative of Delcath Systems, Ltd. and will notify medac accordingly.

11.21. If there are no positive results of the FOCUS trial with respect to the efficacy as defined in the trial protocol, the Parties will, in good faith, discuss ways in which to maintain commercially reasonable viability. For the avoidance of doubt in this case medac is not obliged to pay the respective instalment according to Article 4.1.

11.22. Delcath will inform medac about any changes in information material relating to the PRODUCT.

12. Third party rights and enforcement of IP against third parties

12.1. To the best of Delcath's knowledge, the execution of this Agreement by Delcath and/or medac, in particular the distribution/commercialisation of the PRODUCT in the TERRITORY, the manufacture of the PRODUCT in the country of manufacture, of batch release, of storage or importing the PRODUCT do not infringe any third party INTELLECTUAL PROPERTY rights. All relevant INTELLECTUAL PROPERTY rights were provided by Delcath in September 2017 and there were no relevant updates, e.g. concerning divisional applications. If needed by medac, Delcath will provide medac with further documents and data to perform future IP checks. If medac infringes any third party INTELLECTUAL PROPERTY rights due to incorrect or missing information provided by Delcath, Delcath shall fully indemnify medac of any costs including lawyers' fees occurring in this regard.

12.2. If medac is charged with the infringement of third party rights based on the execution of this Agreement, then medac shall immediately inform Delcath about this allegation. In this case Delcath has the obligation to support medac in any way and provide help to counterclaim; especially if analyses are requested on the PRODUCT provided by Delcath and/ or any data on the PRODUCT or the manufacturing process of the PRODUCT and will pay reasonable costs incurred by medac in defense of any such charge.

12.3. Delcath shall be solely responsible for the prosecution and maintenance of the underlying INTELLECTUAL PROPERTY OF DELCATH of the PRODUCT and for the conduct of any claims or proceedings relating to the INTELLECTUAL PROPERTY OF DELCATH including any validity challenges of third parties, nullity or opposition proceedings. Delcath shall keep medac reasonably informed at all times as to the status of the prosecution and maintenance of all INTELLECTUAL PROPERTY OF DELCATH and in any event providing a written update if requested by medac.

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Delcath shall enforce and defend the underlying INTELLECTUAL PROPERTY OF DELCATH of the PRODUCT at its own cost and expense, if such defence is judged by the patent attorneys in power as promising. medac shall fully co-operate with Delcath and its legal counsel, or otherwise assist in such proceedings. Delcath shall keep medac and its counsel reasonably informed at all times as to the status of the proceedings.

If Delcath fails to enforce or defend the underlying INTELLECTUAL PROPERTY OF DELCATH of the PRODUCT within ten (10) days of becoming aware or of being notified of the same, then, medac may without prejudice to any other right it may have under this Agreement or otherwise give Delcath written notice requiring Delcath to take such proceedings within five (5) days of the date of the notice. If Delcath fails to do so, medac shall be entitled to enforce or defend the underlying INTELLECTUAL PROPERTY OF DELCATH of the PRODUCT at its cost and expense. The reasonable costs of any such settlement (including, without limitation, damages, legal costs, lump sums or other amounts) or, if no settlement is reached, of any judgement or award made against medac or its AFFILIATES, distributors or sublicenses, may be set off by medac against the PRICE payable by medac hereunder. However, medac shall only be entitled to a reimbursement if it can demonstrate that Delcath has wrongfully assessed insufficient prospects of success. Delcath shall provide all reasonable assistance to medac in relation to such proceedings at its own cost and expenses in a timely manner. Delcath is aware of the fact that especially in Germany but also in the further TERRITORY effective remedies against IP-infringements require immediate legal actions.

### 13. Term and Termination

13.1. This Agreement becomes effective on the EFFECTIVE DATE and the supply of the PRODUCT shall continue for a period of seven (7) years starting with the first delivery of the PRODUCT. After the initial term the Parties intend to renew this agreement for another five (5) years. They will negotiate this in good faith at least six months in advance of expiry of the initial term.

**[\*]**

- 13.2. Either Party shall be entitled, by notice to the other, to terminate this Agreement immediately only, if
- the other Party loses a necessary approval for importing, manufacture, marketing or selling of the PRODUCT;
  - the other Party culpably commits or permits a material breach or default of any of the provisions of this Agreement and fails to remedy or cure such breach or default within sixty (60) calendar days after written notice of such breach has been received;
  - the other Party should be dissolved, becomes insolvent, bankrupt or otherwise be faced with circumstances reasonably warranting the conclusion that the Party will not be able within the foreseeable future, to adequately comply with its obligations under this agreement;
  - **[\*]**

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- in case of Force Majeure Event as described in Article 14.

13.3. Either Party may terminate this Agreement because of an uncured breach provided the Party claiming a breach gives the other Party 50 day advanced written notice of such breach and the possibility to remedy such breach.

**[\*]**

b) with immediate effect by medac:

- in the event that any health authority and/or a competent court takes any action, or raises any objection, that prevents medac from commercialising the PRODUCT in the TERRITORY. Additionally, medac will have the right to terminate this Agreement immediately in the event that the PRODUCT cannot be reasonably commercialised for medical or scientific reasons in the TERRITORY, unless a remedy is impossible neither of these 2 events is grounds for termination by medac if they are remedied within 60 days of written notification to Delcath of either events and the grounds on which the event is based;
- in the event of an INTELLECTUAL PROPERTY infringement claim brought by any third party against medac or Delcath (or its subcontractor) which prevents or hinders the commercialisation, manufacture of the PRODUCT or which prevents medac or Delcath from exercising its obligations hereunder.

13.4. **[\*]**

13.5. At the sole discretion of medac, medac may resell any remaining non-expired PRODUCT to Delcath at the purchase price, and may assign to Delcath any trademarks obtained for the PRODUCT against a reasonable consideration payable by Delcath, which shall at the minimum cover the costs of medac for obtaining and maintaining the trademarks.

13.6. Orders placed and confirmed and for which manufacture has started prior to the date of termination shall remain valid (except in the event of termination by for breach by Delcath pursuant to Article 11.3 or in the event of termination for quality failure), and for other orders placed by medac but not confirmed by Delcath, or for which manufacture has not started as of the termination date, the Parties shall discuss and agree on whether they shall remain valid or shall be cancelled.

13.7. The expiry or termination of this Agreement for any reason shall not affect the rights and obligations of the Parties already accrued prior to the effective date of expiry or termination of the Agreement.

13.8. **[\*]**

13.9. Termination or expiration of this Agreement will not relieve either Party of any obligation accruing prior to such expiration or termination, including any breach of such obligations, and all provisions which are expressed to or by implication survive this Agreement will remain in full force and effect. (Provisions relating to Confidentiality, Indemnification and Liabilities; APPLICABLE LAWS, Quality, Effect of termination and INTELLECTUAL PROPERTY shall survive expiration or termination of this Agreement).

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13.10. **[\*]**

14. Force Majeure

14.1. The Parties hereto shall not be responsible for any damage if the performance of all or parts of this Agreement is hindered or prevented by causes beyond the performing Party's control and without its fault or negligence, including, but not limited to, acts of God or acts, laws, orders or regulations of any government or department or agency thereof acting in either its sovereign or contractual capacity, fires, floods, machinery breakages, strikes, work stoppages or other job actions, freight embargoes, boycotts, riots and wars.

14.2. Either Party may, in the event that any Force Majeure cannot be removed or overcome within three (3) months from the date the Party affected first became affected, at the expiration of this period by notice to the other Party terminate this Agreement.

15. Confidentiality

15.1. The Parties agree to keep secret and not to communicate all CONFIDENTIAL INFORMATION. The Parties shall disclose such CONFIDENTIAL INFORMATION only to those employees, agents, etc. who have a need to know and only if such employees, agents etc. are bound by confidential obligations comparable to this provision.

15.2. This secrecy obligation does not apply to any information of which the receiving Party can prove by written documents that it

- was known to the public at the time of the receiving Party's receipt;
- was lawfully received by the Party from a third Party who has no obligation of Confidentiality to the disclosing Party;
- was independently developed by the Party or available to it prior to this agreement;
- was released from the restrictions of this provision by the express prior written consent of the disclosing Party; or
- has been disclosed in compliance with any legal requirement, provided that the disclosing Party has notified the other Party prior to the disclosure of the information and provided that the Party shall disclose only the minimum amount of information required for the purpose of the said legal requirement;

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- 15.3. This provision shall continue in full force and effect, notwithstanding the expiration or termination of this Agreement for any reason for a period of five (5) years after expiration/termination.
- 15.4. Notwithstanding the above provisions of this Article 14, medac shall be free to disclose the information received from Delcath i) to any AFFILIATES, or ii) in the course of executing the Agreement or in anticipation of termination or expiration of this Agreement, to any consultant or sub-contractor of its choosing; or iii) to the health authorities; or iv) to any third party provided such disclosure is necessary to achieve the purpose of this Agreement. Any party to whom medac discloses the information will be bound to the same confidentiality obligations as set forth herein.
16. Miscellaneous
- 16.1 The Parties hereto agree that in connection with this Agreement the status of each of them in relation to the others is that of an independent trader acting in its own name and for its own account. Accordingly, none of the Parties has, or will be considered to have, any power of authority to act as an agent or representative of the other Party, nor have any power of authority to contract in the name, or create or assume any obligation or liability against, or otherwise legally bind the other Party in any way for any purpose, unless otherwise expressly provided herein. All costs and expenses connected with each Party's activities and performance under this Agreement are to be borne solely by the Party incurring such costs and expenses.
- 16.2 The general terms and conditions of both Parties shall be excluded, even if specific reference is made in respective order forms, order confirmations etc.
- 16.3 The failure by any Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute a waiver of the same or affect the validity of this Agreement or any part hereof, or that Party's right thereafter to enforce or to exercise the same. No waiver by a Party shall be valid or binding unless in writing and signed by a duly authorised representative of the waiving Party.
- 16.4 Other than a change of control, the Parties shall not assign any of their rights or obligations hereunder without the prior written consent of the other Party, provided that medac may assign all rights and obligations hereunder to any of its AFFILIATES.
- 16.5 The fulfilment of contractual rights and obligations arising out of this Agreement is subject to the compliance with (a) all requirements medac as a registered AEO (Authorised Economic Operator) is obliged to fulfil and to request from Delcath and (b) all relevant national and international regulations including but not limited to required export/import licenses, shipment authorisations, foreign trade legislation requirements or releases by the competent authorities and embargo or export/import regulations.
- 16.6 The Parties hereto acknowledge that this Agreement and possible future written amendments hereto set forth the entire Agreement.

- 16.7 Modifications of this Agreement have to be made in writing. This applies to this modification provision as well.
- 16.8 This Agreement is construed in accordance with and shall exclusively be governed by the laws of [\*]. The [\*] and [\*] shall not apply.
- 16.9 All disputes, controversies or claims arising out of or in connection with this contract, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration (LCIA), which Rules are deemed to be incorporated by reference into this clause. The arbitration shall be before a single arbitrator mutually agreed upon by the Parties who shall interpret this Agreement in accordance with the laws of England. The seat of the arbitration shall be in London. The language to be used in the arbitration shall be English.
- 16.10 Should provisions of the present Agreement not be legally effective, completely or partially, or later lose their legal effectiveness, the validity of the remaining provisions of the contract shall not thereby be affected. Instead of the ineffective provision an appropriate provision shall be inserted, which – as far as legally permitted – comes close to that which the contracting Parties wanted or is nearest in meaning to their intended economic purpose.
- 16.11 During the Term, medac shall not market, promote or sell within the TERRITORY any other percutaneous hepatic perfusion devices intended to deliver a therapy directly (as opposed to systemically) into the liver and specifically reimbursed for the same indications as the PRODUCT.

Galway, date:

For and behalf of  
Delcath Ltd.

/s/ Jennifer K. Simpson

Jennifer K. Simpson  
Director

Wedel, date:

For and behalf of  
medac GmbH

/s/Heiner Will

Heiner Will  
CMO

/s/Jorg Hans

Jörg Hans  
CEO

/s/Bergit Buettner

Bergit Buettner  
Legal Council

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License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th

Schedule 1: Product, Price

Schedule 2: Supply chain at effective date

Schedule 3: Package Size

Schedule 4: Customer Transition Plan

**License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th**

**[\*]**

Within **[\*]** during the Term, medac shall submit a report of the NET SALES of the preceding quarter to Delcath including the quantity of the sold PRODUCT (PS) differentiated by the respective countries of the TERRITORY. Simultaneously, medac will, by wire transfer, send to Delcath an amount calculated according to the calculation schemes above.

medac shall keep a true and accurate accountancy and record all relevant data to illustrate the NET SALES pursuant to the generally accepted guidelines of the accountancy.

In accordance with Article 7 of this Agreement, Delcath shall have the right to inspect these books by an independent public account at reasonable times and to such an extent as will not interfere with normal operations of medac. The costs for such an audit shall be borne by Delcath. However, in case of the discovery of any inaccuracies the costs shall be borne by medac.

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**License, Supply and Marketing Agreement – Delcath/medac\_2018 December 10th**

Schedule 2: SUPPLY CHAIN AT EFFECTIVE DATE

Company	Address	Activity
Delcath Systems, Inc.	566 Queensbury Avenue Queensbury, NY 12804 USA	Design, manufacture, distribution of sterile hepatic drug delivery and filtration devices
Delcath Systems, Inc	95 Park Rd. Queensbury, NY 12804 USA	Design, manufacture (packaging, labelling and final release) and distribution of sterile hepatic drug delivery and filtration devices
Delcath Systems, Ltd	Unit 19 – Mervue Business Park Galway Ireland	Manufacture (packaging, labelling and final release) and distribution of sterile hepatic drug delivery and filtration devices
Donawa Consulting S.r.l.	Piazza Albania 10, 00153 Roma Italy	EU representative

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[\*]

[\*] Confidential Treatment Requested

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#### Schedule 4: CUSTOMER TRANSITION PLAN

Within 10 business days following execution of this Agreement and receipt of initial exclusive marketing license upfront fee, Delcath will provide medac with a list of present customers by country, purchasing decision makers and related key people and contact coordinates for each along with a purchasing history. In the same period, Delcath will also provide medac with a list of prospective customers, a brief history of interaction, and key people and contact coordinates for each.

If not already provided, Delcath will provide medac with copies of all sales and marketing materials used in each country. Within 20 business days after receipt of these materials from Delcath, medac will provide its plan for sales and marketing materials and anticipated timing for use in the market as they will be subject to Delcath' approval.

On or about **[\*]**, Delcath will notify present and prospective customers that medac will be marketing Chemosat in Europe and will introduce the appropriate medac personnel to said present and prospective customers.

Delcath to provide reasonable support to medac sales efforts through existing Delcath Sales staff for as long as feasible.

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## EXCHANGE AGREEMENT

This Exchange Agreement (the “**Agreement**”) is entered into as of the \_\_\_\_ day of December, 2018, by and between Delcath Systems, Inc., a Delaware corporation with offices located at 1633 Broadway, Suite 22C, New York, New York 10019 (the “**Company**”) and the investor signatory hereto (the “**Holder**”), with reference to the following facts:

A. The Company issued to Holder that certain Warrant to Purchase Common Stock (the “**Existing Warrant**”), issued to the Holder on February 9, 2018, pursuant to (i) that certain Placement Agency Agreement (the “**Placement Agency Agreement**”), dated February 8, 2018, (ii) the Company’s Registration Statement on Form S-1 (File number 333-220898) and (iii) the Company’s final prospectus dated as of February 8, 2018 (the “**Final Prospectus**”) pursuant to, issued on February 9, 2018 and which Existing Warrant is currently exercisable into \_\_\_\_\_ (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events) shares of Common Stock (as defined in the Existing Warrant).

B. The Company and the Holder desire to issue such aggregate number of shares of Common Stock as set forth on the signature page of the Holder (the “**Exchange Shares**”) in exchange for the Existing Warrant (collectively, the “**Exchange**” or the “**Transaction**”). The Exchange Shares, the Leak-Out Agreement (as defined below) and this Agreement and such other documents and certificates related thereto are collectively referred to herein as the “**Exchange Documents**”.

C. The Exchange is being made in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the “**1933 Act**”).

D. Capitalized terms used but not otherwise defined herein shall have the meanings set forth in the Existing Warrant.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants hereinafter contained, the parties hereto agree as follows:

1. **Exchange.** On the date hereof, pursuant to Section 3(a)(9) of the 1933 Act, the Holder hereby agrees to convey, assign and transfer the Existing Warrant to the Company in exchange for which the Company agrees to issue the Exchange Shares to the Holder. On the date hereof, in exchange for the Existing Warrant, the Company shall deliver (a) the Exchange Shares to the Holder by deposit/withdrawal at custodian in accordance with the instructions attached hereto as **Schedule I**, which Exchange Shares shall be issued without restricted legend and shall be freely tradable by the Holder. Concurrently herewith, the Holder has executed and delivered to the Company a leak-out agreement, in the form attached hereto as **Exhibit A** (the “**Leak-Out Agreement**”).

2. **No Amendment or Waiver.** Nothing herein shall amend, modify or waive any term or condition in any agreement by and between the Company and the Holder or any security issued by the Company to the Holder.

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3. **Representations and Warranties.** As of the date hereof:

3.1 **Organization and Qualification.** Each of the Company and each of its Subsidiaries are entities duly organized and validly existing and in good standing under the laws of the jurisdiction in which they are formed, and have the requisite power and authority to own their properties and to carry on their business as now being conducted and as presently proposed to be conducted. Each of the Company and each of its Subsidiaries is duly qualified as a foreign entity to do business and is in good standing in every jurisdiction in which its ownership of property or the nature of the business conducted by it makes such qualification necessary, except to the extent that the failure to be so qualified or be in good standing would not reasonably be expected to have a Material Adverse Effect (as defined below). As used in this Agreement, “**Material Adverse Effect**” means any material adverse effect on (i) the business, properties, assets, liabilities, operations (including results thereof), condition (financial or otherwise) or prospects of the Company or any Subsidiary, individually or taken as a whole, (ii) the transactions contemplated hereby or in any of the other Transaction Documents or (iii) the authority or ability of the Company or any of its Subsidiaries to perform any of their respective obligations under any of the Transaction Documents (as defined below). Other than the Persons (as defined below) listed in the SEC Documents, the Company has no Subsidiaries. “**Subsidiaries**” means any Person in which the Company, directly or indirectly, (I) owns any of the outstanding capital stock or holds any equity or similar interest of such Person or (II) controls or operates all or any part of the business, operations or administration of such Person, and each of the foregoing, is individually referred to herein as a “**Subsidiary.**” For purposes of this Agreement, (x) “**Person**” means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and any Governmental Entity or any department or agency thereof and (y) “**Governmental Entity**” means any nation, state, county, city, town, village, district, or other political jurisdiction of any nature, federal, state, local, municipal, foreign, or other government, governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official, or entity and any court or other tribunal), multi-national organization or body; or body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature or instrumentality of any of the foregoing, including any entity or enterprise owned or controlled by a government or a public international organization or any of the foregoing.

3.2 **Authorization and Binding Obligation.** The Company has the requisite power and authority to enter into and perform its obligations under this Agreement and each of the other agreements entered into by the parties hereto in connection with the transactions contemplated by the Exchange Documents and to consummate the Transaction (including, without limitation, the issuance of the Exchange Shares in accordance with the terms hereof). The execution and delivery of the Exchange Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby, including, without limitation, the issuance of the Exchange Shares has been duly authorized by the Company’s Board of Directors and no further filing, consent, or authorization is required by the Company, its Board of Directors or its stockholders. This Agreement and the other Exchange Documents have been duly executed and delivered by the Company, and constitute the legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except as such enforceability may be limited by general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of applicable creditors’ rights and remedies and except as rights to indemnification and to contribution may be limited by federal or state securities laws.

3.3 No Conflict. Except as set forth on Schedule 3.3, the execution, delivery and performance of the Exchange Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the issuance of the Exchange Shares) will not (i) result in a violation of the Certificate of Incorporation (as defined below) or any other organizational documents of the Company or any of its Subsidiaries, any capital stock of the Company or any of its Subsidiaries or Bylaws (as defined below) of the Company or any of its Subsidiaries, (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including foreign, federal and state securities laws and regulations and the rules and regulations of the OTCQB (the “**Principal Market**”) and including all applicable federal laws, rules and regulations) applicable to the Company or any of its Subsidiaries or by which any property or asset of the Company or any of its Subsidiaries is bound or affected except, in the case of clause (ii) or (iii) above, to the extent such violations that would not reasonably be expected to have a Material Adverse Effect.

3.4 No Consents. Neither the Company nor any Subsidiary is required to obtain any consent from, authorization or order of, or make any filing or registration with (other than the filing with the Securities and Exchange Commission (the “**SEC**”) of a Form D with the SEC, any other filings as may be required by any state securities agencies, filing of UCC financing statements and approval by the Principal Market of a listing of additional shares application in respect of the Exchange Shares as required by Section 7 hereof), any court, governmental agency or any regulatory or self-regulatory agency or any other Person in order for it to execute, deliver or perform any of its respective obligations under or contemplated by the Exchange Documents, in each case, in accordance with the terms hereof or thereof. All consents, authorizations, orders, filings and registrations which the Company or any Subsidiary is required to obtain pursuant to the preceding sentence have been obtained or effected on or prior to the date hereof, and neither the Company nor any of its Subsidiaries are aware of any facts or circumstances which might prevent the Company or any of its Subsidiaries from obtaining or effecting any of the registration, application or filings contemplated by the Exchange Documents. Except as disclosed in the SEC Documents, the Company is not in violation of the requirements of the Principal Market and has no knowledge of any facts or circumstances which would reasonably lead to delisting or suspension of the Common Stock in the foreseeable future.

3.5 Securities Law Exemptions. Assuming the accuracy of the representations and warranties of the Holder contained herein, the offer and issuance by the Company of the Exchange Shares is exempt from registration under the 1933 Act pursuant to the exemption provided by Rule 3(a)(9) thereof.

3.6 Issuance of Exchange Shares. The issuance of the Exchange Shares has been duly authorized and upon issuance in accordance with the terms of the Exchange Documents, the Exchange Shares will be validly issued, fully paid and nonassessable and free from all Liens with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock. By virtue of Rule 3(a)(9) under the 1933 Act, each of the Exchange Shares shall be freely tradeable and shall not bear any restrictive legends.

3.7 Transfer Taxes. On the date hereof, all share transfer or other taxes (other than income or similar taxes) which are required to be paid in connection with the issuance of the Exchange Shares to be exchanged with the Holder hereunder will be, or will have been, fully paid or provided for by the Company, and all laws imposing such taxes will be or will have been complied with.

3.8 SEC Documents; Financial Statements. During the two (2) years prior to the date hereof, the Company has timely filed all reports, schedules, forms, proxy statements, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the 1934 Act (all of the foregoing filed prior to the date hereof, including without limitation, Current Reports on Form 8-K filed by the Company with the SEC whether required to be filed or not (but excluding Item 7.01 thereunder), and all exhibits and appendices included therein (other than Exhibits 99.1 to Form 8-K) and financial statements, notes and schedules thereto and documents incorporated by reference therein being hereinafter referred to as the “**SEC Documents**”). The Company has delivered or has made available to the Holder or its representatives true, correct and complete copies of each of the SEC Documents not available on the EDGAR system. As of their respective dates, the SEC Documents complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. As of their respective dates, the financial statements of the Company included in the SEC Documents complied in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto as in effect as of the time of filing. Such financial statements have been prepared in accordance with generally accepted accounting principles (“**GAAP**”), consistently applied, during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments which will not be material, either individually or in the aggregate). No other information provided by or on behalf of the Company to the Holder which is not included in the SEC Documents (including, without limitation, information in the disclosure schedules to this Agreement) contains any untrue statement of a material fact or omits to state any material fact necessary in order to make the statements therein not misleading, in the light of the circumstance under which they are or were made. The Company is not currently contemplating to amend or restate any of the financial statements (including, without limitation, any notes or any letter of the independent accountants of the Company with respect thereto) included in the SEC Documents (the “**Financial Statements**”), nor is the Company currently aware of facts or circumstances which would require the Company to amend or restate any of the Financial Statements, in each case, in order for any of the Financials Statements to be in compliance with GAAP and the rules and regulations of the SEC. The Company has not been informed by its independent accountants that they recommend that the Company amend or restate any of the Financial Statements or that there is any need for the Company to amend or restate any of the Financial Statements.

3.9 Absence of Certain Changes. Except as set forth in the SEC Documents, since the date of the Company's most recent audited financial statements contained in a Form 10-K, there has been no material adverse change and no material adverse development in the business, assets, liabilities, properties, operations (including results thereof), condition (financial or otherwise) or prospects of the Company or any of its Subsidiaries. Since the date of the Company's most recent audited financial statements contained in a Form 10-K, neither the Company nor any of its Subsidiaries has (i) declared or paid any dividends, (ii) sold any assets, individually or in the aggregate, outside of the ordinary course of business or (iii) except as disclosed in the SEC Documents, made any capital expenditures, individually or in the aggregate, outside of the ordinary course of business. Neither the Company nor any of its Subsidiaries has taken any steps to seek protection pursuant to any law or statute relating to bankruptcy, insolvency, reorganization, receivership, liquidation or winding up, nor does the Company or any Subsidiary have any knowledge or reason to believe that any of their respective creditors intend to initiate involuntary bankruptcy proceedings or any actual knowledge of any fact which would reasonably lead a creditor to do so. The Company and its Subsidiaries, individually and on a consolidated basis, are not as of the date hereof, and after giving effect to the transactions contemplated hereby to occur on the date hereof, will not be Insolvent (as defined below). For the purpose of this Agreement (x) "**Insolvent**" means, (i) with respect to the Company and its Subsidiaries, on a consolidated basis, (A) the present fair saleable value of the Company's and its Subsidiaries' assets is less than the amount required to pay the Company's and its Subsidiaries' total Indebtedness (as defined below), (B) the Company and its Subsidiaries are unable to pay their debts and liabilities, subordinated, contingent or otherwise, as such debts and liabilities become absolute and matured or (C) the Company and its Subsidiaries intend to incur or believe that they will incur debts that would be beyond their ability to pay as such debts mature; and (ii) with respect to the Company and each Subsidiary, individually, (A) the present fair saleable value of the Company's or such Subsidiary's (as the case may be) assets is less than the amount required to pay its respective total Indebtedness, (B) the Company or such Subsidiary (as the case may be) is unable to pay its respective debts and liabilities, subordinated, contingent or otherwise, as such debts and liabilities become absolute and matured or (C) the Company or such Subsidiary (as the case may be) intends to incur or believes that it will incur debts that would be beyond its respective ability to pay as such debts mature; (y) "**Indebtedness**" of any Person means, without duplication (A) all indebtedness for borrowed money, (B) all obligations issued, undertaken or assumed as the deferred purchase price of property or services (including, without limitation, "capital leases" in accordance with GAAP) (other than trade payables entered into in the ordinary course of business consistent with past practice), (C) all reimbursement or payment obligations with respect to letters of credit, surety bonds and other similar instruments, (D) all obligations evidenced by notes, bonds, debentures or similar instruments, including obligations so evidenced incurred in connection with the acquisition of property, assets or businesses, (E) all indebtedness created or arising under any conditional sale or other title retention agreement, or incurred as financing, in either case with respect to any property or assets acquired with the proceeds of such indebtedness (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property), (F) all monetary obligations under any leasing or similar arrangement which, in connection with GAAP, consistently applied for the periods covered thereby, is classified as a capital lease, (G) all indebtedness referred to in clauses (A) through (F) above secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in any property or assets (including accounts and contract rights) owned by any Person, even though the Person which owns such assets or property has not assumed or become liable for the payment of such indebtedness, and (H) all Contingent Obligations in respect of indebtedness or obligations of others of the kinds referred to in clauses (A) through (G) above; and (z) "**Contingent Obligation**" means, as to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to any Indebtedness, lease, dividend or other obligation of another Person if the primary purpose or intent of the Person incurring such liability, or the primary effect thereof, is to provide assurance to the obligee of such liability that such liability will be paid or discharged, or that any agreements relating thereto will be complied with, or that the holders of such liability will be protected (in whole or in part) against loss with respect thereto.

3.10 No Undisclosed Events, Liabilities, Developments or Circumstances. Except as set forth in the SEC Documents, no event, liability, development or circumstance has occurred or exists, or is reasonably expected to exist or occur with respect to the Company, any of its Subsidiaries or any of their respective businesses, properties, liabilities, prospects, operations (including results thereof) or condition (financial or otherwise), that (i) would be required to be disclosed by the Company under applicable securities laws on a registration statement on Form S-1 filed with the SEC relating to an issuance and sale by the Company of its Common Stock and which has not been publicly announced, (ii) would reasonably be expected to have a material adverse effect on the Holder's investment hereunder or (iii) would reasonably be expected to have a Material Adverse Effect.

3.11 Conduct of Business; Regulatory Permits. Neither the Company nor any of its Subsidiaries is in violation of any term of or in default under its Certificate of Incorporation, any certificate of designation, preferences or rights of any other outstanding series of preferred stock of the Company or any of its Subsidiaries or Bylaws or their organizational charter, certificate of formation, memorandum of association, articles of association, Certificate of Incorporation or bylaws, respectively. Except as set forth in the SEC Documents, neither the Company nor any of its Subsidiaries is in violation of any judgment, decree or order or any statute, ordinance, rule or regulation applicable to the Company or any of its Subsidiaries, and neither the Company nor any of its Subsidiaries will conduct its business in violation of any of the foregoing, except in all cases for possible violations which could not, individually or in the aggregate, have a Material Adverse Effect. Except as set forth in the SEC Documents, without limiting the generality of the foregoing, the Company is not in violation of any of the rules, regulations or requirements of the Principal Market and has no knowledge of any facts or circumstances that could reasonably lead to delisting or suspension of the Common Stock by the Principal Market in the foreseeable future. During the two years prior to the date hereof, (i) the Common Stock has been listed or designated for quotation on the Principal Market, (ii) trading in the Common Stock has not been suspended by the SEC or the Principal Market and (iii) the Company has received no communication, written or oral, from the SEC or the Principal Market regarding the suspension or delisting of the Common Stock from the Principal Market. The Company

and each of its Subsidiaries possess all certificates, authorizations and permits issued by the appropriate regulatory authorities necessary to conduct their respective businesses, except where the failure to possess such certificates, authorizations or permits would not have, individually or in the aggregate, a Material Adverse Effect, and neither the Company nor any such Subsidiary has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit. There is no agreement, commitment, judgment,

injunction, order or decree binding upon the Company or any of its Subsidiaries or to which the Company or any of its Subsidiaries is a party which has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company or any of its Subsidiaries, any acquisition of property by the Company or any of its Subsidiaries or the conduct of business by the Company or any of its Subsidiaries as currently conducted other than such effects, individually or in the aggregate, which have not had and would not reasonably be expected to have a Material Adverse Effect on the Company or any of its Subsidiaries.

3.12 Transactions With Affiliates. Except as set forth in the SEC Documents, no current or former employee, partner, director, officer or stockholder (direct or indirect) of the Company or its Subsidiaries, or any associate, or, to the knowledge of the Company, any affiliate of any thereof, or any relative with a relationship no more remote than first cousin of any of the foregoing, is presently, or has ever been, (i) a party to any transaction with the Company or its Subsidiaries (including any contract, agreement or other arrangement providing for the furnishing of services by, or rental of real or personal property from, or otherwise requiring payments to, any such director, officer or stockholder or such associate or affiliate or relative Subsidiaries (other than for ordinary course services as employees, consultants, officers or directors of the Company or any of its Subsidiaries)) or (ii) the direct or indirect owner of an interest in any corporation, firm, association or business organization which is a competitor, supplier or customer of the Company or its Subsidiaries (except for a passive investment (direct or indirect) in less than 5% of the common stock of a company whose securities are traded on or quoted through an Eligible Market), nor does any such Person receive income from any source other than the Company or its Subsidiaries which relates to the business of the Company or its Subsidiaries or should properly accrue to the Company or its Subsidiaries. No employee, officer, stockholder or director of the Company or any of its Subsidiaries or member of his or her immediate family is indebted to the Company or its Subsidiaries, as the case may be, nor is the Company or any of its Subsidiaries indebted (or committed to make loans or extend or guarantee credit) to any of them, other than (i) for payment of salary for services rendered, (ii) reimbursement for reasonable expenses incurred on behalf of the Company, and (iii) for other standard employee benefits made generally available to all employees or executives (including stock option agreements outstanding under any stock option plan approved by the Board of Directors of the Company).

3.13 Equity Capitalization.

(a) Definitions:

(i) **“Common Stock”** means (x) the Company’s shares of common stock, \$0.01 par value per share, and (y) any capital stock into which such common stock shall have been changed or any share capital resulting from a reclassification of such common stock.

(ii) **“Preferred Stock”** means (x) the Company’s blank check preferred stock, \$0.01 par value per share, the terms of which may be designated by the board of directors of the Company in a certificate of designations and (y) any capital stock into which such preferred stock shall have been changed or any share capital resulting from a reclassification of such preferred stock (other than a conversion of such preferred stock into Common Stock in accordance with the terms of such certificate of designations).

(b) Authorized and Outstanding Capital Stock. As of the date hereof, the authorized capital stock of the Company consists of (A) 1.0 billion shares of Common Stock, of which, 9.0 million are issued and outstanding as of the date hereof and 71.1 million are reserved for issuance pursuant to Convertible Securities (as defined below), in each case exercisable or exchangeable for, or convertible into, shares of Common Stock, and (B) 10.0 million shares of Preferred Stock, of which 85 shares are issued and outstanding. One share of Common Stock is held in the treasury of the Company. **“Convertible Securities”** means any capital stock or other security of the Company or any of its Subsidiaries that is at any time and under any circumstances directly or indirectly convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any capital stock or other security of the Company (including, without limitation, Common Stock) or any of its Subsidiaries.

(c) Valid Issuance; Available Shares; Affiliates. All of such outstanding shares are duly authorized and have been, or upon issuance will be, validly issued and are fully paid and nonassessable. Schedule 3.13 sets forth the number of shares of Common Stock that are (A) reserved for issuance pursuant to Convertible Securities and (B) that are, as of the date hereof, owned by Persons who are “affiliates” (as defined in Rule 405 of the 1933 Act and calculated based on the assumption that only officers, directors and holders of at least 10% of the Company’s issued and outstanding Common Stock are “affiliates” without conceding that any such Persons are “affiliates” for purposes of federal securities laws) of the Company or any of its Subsidiaries.

(d) Existing Securities; Obligations. Except as disclosed in the SEC Documents: (A) none of the Company’s or any Subsidiary’s shares, interests or capital stock is subject to from all preemptive or similar rights, mortgages, defects, claims, liens, pledges, charges, taxes, rights of first refusal, encumbrances, security interests and other encumbrances (collectively **“Liens”**) suffered or permitted by the Company or any Subsidiary; (B) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, or exercisable or exchangeable for, any shares, interests or capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares, interests or capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, or exercisable or exchangeable for, any shares, interests or capital stock of the Company or any of its Subsidiaries; (C) there are no agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the 1933 Act; (D) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries; (E) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Exchange Shares; and (F) neither the Company nor any Subsidiary has any stock appreciation rights or “phantom stock” plans or agreements or any similar plan or agreement.



(e) Organizational Documents. The Company has furnished to the Holder true, correct and complete copies of the Company's Certificate of Incorporation, as amended and as in effect on the date hereof (the "**Certificate of Incorporation**"), and the Company's bylaws, as amended and as in effect on the date hereof (the "**Bylaws**"), and the terms of all Convertible Securities and the material rights of the holders thereof in respect thereto.

3.14 Indebtedness and Other Contracts. Neither the Company nor any of its Subsidiaries, (i) except as disclosed in the SEC Documents or Schedule 3(s) of the Securities Purchase Agreement, has any outstanding debt securities, notes, credit agreements, credit facilities or other agreements, documents or instruments evidencing Indebtedness of the Company or any of its Subsidiaries or by which the Company or any of its Subsidiaries is or may become bound, (ii) is a party to any contract, agreement or instrument, except as disclosed in the SEC Documents, the violation of which, or default under which, by the other party(ies) to such contract, agreement or instrument could reasonably be expected to result in a Material Adverse Effect, (iii) has any financing statements securing obligations in any amounts filed in connection with the Company or any of its Subsidiaries, except as disclosed in the SEC Documents; (iv) is in violation of any term of, or in default under, any contract, agreement or instrument relating to any Indebtedness, except where such violations and defaults would not result, individually or in the aggregate, in a Material Adverse Effect, or (v) is a party to any contract, agreement or instrument relating to any Indebtedness, the performance of which, in the judgment of the Company's officers, has or is expected to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries have any liabilities or obligations required to be disclosed in the SEC Documents which are not so disclosed in the SEC Documents, other than those incurred in the ordinary course of the Company's or its Subsidiaries' respective businesses and which, individually or in the aggregate, do not or could not have a Material Adverse Effect.

3.15 Litigation. There is no action, suit, arbitration, proceeding, inquiry or investigation before or by the Principal Market, any court, public board, other Governmental Entity, self-regulatory organization or body pending or, to the knowledge of the Company, threatened against or affecting the Company or any of its Subsidiaries, the Common Stock or any of the Company's or its Subsidiaries' officers or directors that would reasonably be expected to have a Material Adverse Effect on the Company or its Subsidiaries, whether of a civil or criminal nature or otherwise, in their capacities as such, except as disclosed in the SEC Documents or in Schedule 3(t) of the Securities Purchase Agreement. No director, officer or employee of the Company or any of its subsidiaries has willfully violated 18 U.S.C. §1519 or engaged in spoliation in reasonable anticipation of litigation. Without limitation of the foregoing, there has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the SEC involving the Company, any of its Subsidiaries or any current or former director or officer of the Company or any of its Subsidiaries. The SEC has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the 1933 Act or the 1934 Act. Neither the Company nor any of its Subsidiaries is subject to any order, writ, judgment, injunction, decree, determination or award of any Governmental Entity.

3.16 Disclosure. The Company confirms that neither it nor any other Person acting on its behalf has provided the Holder or its agents or counsel with any information that constitutes or would reasonably be expected to constitute material, non-public information concerning the Company or any of its Subsidiaries, other than the existence of the transactions contemplated by this Agreement and the other Exchange Documents. The Company understands and confirms that the Holder will rely on the foregoing representations in effecting transactions in securities of the Company. All disclosure provided to the Holder regarding the Company and its Subsidiaries, their businesses and the transactions contemplated hereby, including the schedules to this Agreement, furnished by or on behalf of the Company or any of its Subsidiaries is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. Each press release issued by the Company or any of its Subsidiaries during the twelve (12) months preceding the date of this Agreement did not at the time of release contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they are made, not misleading. No event or circumstance has occurred or information exists with respect to the Company or any of its Subsidiaries or its or their business, properties, liabilities, prospects, operations (including results thereof) or conditions (financial or otherwise), which, under applicable law, rule or regulation, requires public disclosure at or before the date hereof or announcement by the Company but which has not been so publicly announced or disclosed.

4. **Holder's Representations and Warranties**. As a material inducement to the Company to enter into this Agreement and consummate the Exchange, the Holder represents, warrants and covenants with and to the Company as follows:

4.1 Reliance on Exemptions. The Holder understands that the Exchange Shares are being offered and exchanged in reliance on specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying in part upon the truth and accuracy of, and the Holder's compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Holder set forth herein and in the Exchange Documents in order to determine the availability of such exemptions and the eligibility of the Holder to acquire the Exchange Shares.

4.2 No Governmental Review. The Holder understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Exchange Shares or the fairness or suitability of the investment in the Exchange Shares nor have such authorities passed upon or endorsed the merits of the offering of the Exchange Shares.

4.3 Validity; Enforcement. This Agreement and the Exchange Documents to which the Holder is a party have been duly and validly authorized, executed and delivered on behalf of the Holder and shall constitute the legal, valid and binding obligations of the Holder enforceable against the Holder in accordance with their respective terms, except as such enforceability may be limited by general principles of equity or to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies.

4.4 No Conflicts. The execution, delivery and performance by the Holder of this Agreement and the Exchange Documents to which the Holder is a party, and the consummation by the Holder of the transactions contemplated hereby and thereby will not (i) result in a violation of the organizational documents of the Holder or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Holder is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to the Holder, except in the case of clauses (ii) and (iii) above, for such conflicts, defaults, rights or violations which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of the Holder to perform its obligations hereunder.

4.5 Investment Risk; Sophistication. The Holder is acquiring the Exchange Shares hereunder in the ordinary course of its business. The Holder has such knowledge, sophistication, and experience in business and financial matters so as to be capable of evaluation of the merits and risks of the prospective investment in the Exchange Shares, and has so evaluated the merits and risk of such investment. The Holder is an “accredited investor” as defined in Regulation D under the 1933 Act.

4.6 Ownership of Existing Warrant. The Holder owns the Existing Warrant free and clear of any Liens (other than the obligations pursuant to this Agreement and applicable securities laws).

5. Disclosure of Transaction. The Company shall, on or before 8:30 a.m., New York City Time, on or prior to the first business day after the date of this Agreement, file a Current Report on Form 8-K describing the terms of the transactions contemplated hereby in the form required by the 1934 Act and attaching the Exchange Documents, to the extent they are required to be filed under the 1934 Act, that have not previously been filed with the SEC by the Company (including, without limitation, this Agreement) as exhibits to such filing (including all attachments, the “**8-K Filing**”). From and after the filing of the 8-K Filing, the Company shall have disclosed all material, non-public information (if any) provided up to such time to the Holder by the Company or any of its Subsidiaries or any of their respective officers, directors, employees or agents. In addition, effective upon the filing of the 8-K Filing, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement with respect to the transactions contemplated by the Exchange Documents or as otherwise disclosed in the 8-K Filing, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, affiliates, employees or agents, on the one hand, and any of the Holder or any of their affiliates, on the other hand, shall terminate. Neither the Company, its Subsidiaries nor the Holder shall issue any press releases or any other public statements with respect to the transactions contemplated hereby; *provided, however*, the Company shall be entitled, without the prior approval of the Holder, to make a press release or other public disclosure with respect to such transactions (i) in substantial conformity with the 8-K Filing and contemporaneously therewith or (ii) as is required by applicable law and regulations (provided that in the case of clause (i) the Holder shall be consulted by the Company in connection with any such press release or other public disclosure prior to its release). Without the prior written consent of the Holder (which may be granted or withheld in the Holder’s sole discretion), except as required by applicable law, the Company shall not (and shall cause each of its Subsidiaries and affiliates to not) disclose the name of the Holder in any filing, announcement, release or otherwise.

6. **No Integration.** None of the Company, its Subsidiaries, any of their affiliates, or any Person acting on their behalf shall, directly or indirectly, make any offers or sales of any security (as defined in the 1933 Act) or solicit any offers to buy any security or take any other actions, under circumstances that would require registration of any of the Exchange Shares under the 1933 Act or cause this offering of the Exchange Shares to be integrated with such offering or any prior offerings by the Company for purposes of Regulation D under the 1933 Act.

7. **Listing.** The Company shall promptly secure the listing or designation for quotation (as applicable) of all of the Exchange Shares upon the Principal Market (subject to official notice of issuance) and shall maintain such listing of all the Exchange Shares from time to time issuable under the terms of the Exchange Documents. The Company shall maintain the Common Stock's authorization for quotation on the Principal Market. Neither the Company nor any of its Subsidiaries shall take any action which would be reasonably expected to result in the delisting or suspension of the Common Stock on the Principal Market. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 7.

8. **Fees.** Each party to this Agreement shall bear its own expenses in connection with the structuring, documentation, negotiation and closing of the transactions contemplated hereby, except as provided in the previous sentence and except that the Company shall be responsible for the payment of any placement agent's fees, financial advisory fees, transfer agent fees, Depository Trust Company ("**DTC**") fees relating to or arising out of the transactions contemplated hereby.

9. **Holding Period.** For the purposes of Rule 144, the Company acknowledges that the holding period of the Exchange Shares may be tacked onto the holding period of the Existing Warrant, and the Company agrees not to take a position contrary to this Section 9. The Company acknowledges and agrees that (assuming the Holder is not an affiliate of the Company) (i) the Exchange Shares are as of the date hereof, eligible to be resold pursuant to Rule 144, (ii) the Company is not aware of any event reasonably likely to occur that would reasonably be expected to result in the Exchange Shares (assuming the issuance thereof pursuant to a cashless exercise) becoming ineligible to be resold by the Holder pursuant to Rule 144 and (iii) in connection with any resale of any Exchange Shares pursuant to Rule 144, the Holder shall solely be required to provide reasonable assurances that such Exchange Shares are eligible for resale, assignment or transfer under Rule 144, which shall not include an opinion of Holder's counsel. The Company shall be responsible for any transfer agent fees or DTC fees or legal fees of the Company's counsel with respect to the removal of legends, if any, or issuance of Exchange Shares in accordance herewith.

10. **Blue Sky.** The Company shall make all filings and reports relating to the Exchange required under applicable securities or "Blue Sky" laws of the states of the United States following the date hereof, if any.

11. **Most Favored Nation.** The Company hereby represents and warrants as of the date hereof and covenants and agrees from and after the date hereof until the first anniversary of the date hereof, that none of the terms offered to any Person with respect to any consent, release, amendment, settlement or waiver relating to the terms, conditions and transactions contemplated hereby (each a “**Settlement Document**”), is or will be more favorable to such Person than those of the Holder and this Agreement or would otherwise result in such other holder (each, an “**Other Holder**”) of the Existing Warrant (each, a “**Settlement Warrant**”), or its designee, directly or indirectly, acquiring more than (or having the right to acquire more than, as applicable) one share of Common Stock, in exchange for (whether by exchange, reduction, cancelation or any other transaction with respect to) any one share of Common Stock issuable upon exercise (without regard to any cashless exercise) of such Settlement Warrant (a “**Settlement Make-Whole Event**”). If, and whenever on or after the date hereof, the Company enters into a Settlement Document, then (i) the Company shall provide notice thereof to the Holder immediately following the occurrence thereof and (ii) the terms and conditions of this Agreement shall be, without any further action by the Holder or the Company, automatically amended and modified in an economically and legally equivalent manner such that the Holder shall receive the benefit of the more favorable terms and/or conditions (as the case may be) set forth in such Settlement Document and, if a Settlement Make-Whole Event occurs, the Company shall deliver to the Holder, as additional securities issuable pursuant to the Exchange hereunder for the Existing Warrant, such aggregate number of additional shares of Common Stock as equal to the product of (a) \_\_\_\_\_ multiplied by (b) the difference of (i) the quotient of (x) the aggregate number of shares of Common Stock (on an as-converted and as-exercised (without regard to cashless exercise) basis) issued (or issuable to) such Other Holder (or its designee) pursuant to such Settlement Agreement and (y) the aggregate number of shares of Common Stock issuable upon exercise (without regard to any cashless exercise) of the Settlement Warrants subject to reduction, exchange, cancellation or otherwise pursuant to such Settlement Make-Whole Event, less (ii) one (1). Notwithstanding the foregoing, upon written notice to the Company at any time the Holder may elect not to accept the benefit of any such amended or modified term or condition, in which event the term or condition contained in this Agreement shall apply to the Holder as it was in effect immediately prior to such amendment or modification as if such amendment or modification never occurred with respect to the Holder. The provisions of this Section 11 shall apply similarly and equally to each Settlement Document.

12. **Independent Nature of Holder's Obligations and Rights.** The obligations of the Holder under this Agreement are several and not joint with the obligations of any Other Holder, and the Holder shall not be responsible in any way for the performance of the obligations of any Other Holder under any other agreement with the Company (each, an "**Other Agreement**"). Nothing contained herein or in any Other Agreement, and no action taken by the Holder pursuant hereto, shall be deemed to constitute the Holder and Other Holders as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Holder and Other Holders are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by this Agreement or any Other Agreement and the Company acknowledges that, to the best of its knowledge, the Holder and the Other Holders are not acting in concert or as a group with respect to such obligations or the transactions contemplated by this Agreement or any Other Agreement. The Company and the Holder confirm that the Holder has independently participated in the negotiation of the transactions contemplated hereby with the advice of its own counsel and advisors. The Holder shall be entitled to independently protect and enforce its rights, including, without limitation, the rights arising out of this Agreement, and it shall not be necessary for any Other Holder to be joined as an additional party in any proceeding for such purpose.

13. **Miscellaneous Provisions.** Section 9 of the Securities Purchase Agreement is hereby incorporated by reference herein, *mutatis mutandis*.

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**IN WITNESS WHEREOF**, Holders and the Company have executed this Agreement as of the date set forth on the first page of this Agreement.

**COMPANY:**

**DELCATH SYSTEMS, INC.**

By: \_\_\_\_\_

Name: Jennifer K. Simpson

Title: President & CEO

**IN WITNESS WHEREOF**, Holders and the Company have executed this Agreement as of the date set forth on the first page of this Agreement.

**HOLDER:**

\_\_\_\_\_

By:

\_\_\_\_\_  
Name:

Title:

**Aggregate Number of Exchange Shares:**

\_\_\_\_\_



## LEAK-OUT AGREEMENT

December \_\_, 2018

This agreement (the "Leak-Out Agreement") is being delivered to you in connection with an understanding by and among Delcath Systems, Inc., a Delaware corporation (the "Company"), and the person or persons named on the signature pages hereto (collectively, the "Holder").

Reference is hereby made to (a) that certain Warrant Exchange Agreement, dated December \_\_, 2018 (the "Warrant Exchange Agreement"), by and between the Company and the Holder, pursuant to which, among other things, the Holder (in its capacity as a holder of certain Existing Warrants (as defined in the Warrant Exchange Agreement)), acquired certain shares of Common Stock ("Shares") in exchange for such Existing Warrants (the "Warrant Exchange"). Capitalized terms not defined herein shall have the meaning as set forth in the Warrant Exchange Agreement.

The Holder agrees solely with the Company that from the date of issuance of the Shares to the Holder (the "Effective Date") and ending at 4:00 pm (New York City time) on \_\_\_\_\_ \_\_, 20\_\_ (such period, the "Restricted Period"), neither the Holder, nor any Affiliate of such Holder which (x) had or has knowledge of the transactions contemplated by the Warrant Exchange Agreement, (y) has or shares discretion relating to such Holder's investments or trading or information concerning such Holder's investments, including in respect of the Securities, or (z) is subject to such Holder's review or input concerning such Affiliate's investments or trading (together, the "Holder's Trading Affiliates"), collectively, shall sell, dispose or otherwise transfer, directly or indirectly, (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions) on any Trading Day during the Restricted Period (any such date, a "Date of Determination"), shares of Common Stock, or shares of Common Stock underlying any Common Stock Equivalents, held by the Holder on the date hereof, including the Shares (collectively, the "Restricted Securities"), in an amount more than the Holder's Leak-Out Percentage (as defined in that certain Leak-Out Agreement, dated \_\_\_\_\_ \_\_, 20\_\_, by and between the Company and the Holder (such percentage, the "February Leak-Out Percentage"), which for the Holder is \_\_\_% of the trading volume of Common Stock as reported by Bloomberg, LP for the applicable Date of Determination ("Leak-Out Percentage").

Notwithstanding anything herein to the contrary, until the end of the Restricted Period the Holder may, directly or indirectly, sell or transfer all, or any part, of any Restricted Securities to any Person (an "Assignee") in a transaction which does not need to be reported on the consolidated tape on the Trading Market, without complying with (or otherwise limited by) the restrictions set forth in this Leak-Out Agreement; provided, that as a condition to any such sale or transfer an authorized signatory of the Company and such Assignee duly execute and deliver a leak-out agreement in the form of this Leak-Out Agreement (an "Assignee Agreement", and each such transfer a "Permitted Transfer") and, subsequent to a Permitted Transfer, sales of the Holder and the Holder's Trading Affiliates and all Assignees (other than any such sales that constitute Permitted Transfers) shall be aggregated for all purposes of this Leak-Out Agreement and all Assignee Agreements.

Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Leak-Out Agreement must be in writing and shall be given in accordance with the terms of the SPA.

This Leak-Out Agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof and supersedes all prior negotiations, letters and understandings relating to the subject matter hereof and are fully binding on the parties hereto.

This Leak-Out Agreement may be executed simultaneously in any number of counterparts. Each counterpart shall be deemed to be an original, and all such counterparts shall constitute one and the same instrument. This Leak-Out Agreement may be executed and accepted by facsimile or PDF signature and any such signature shall be of the same force and effect as an original signature.

The terms of this Leak-Out Agreement shall be binding upon and shall inure to the benefit of each of the parties hereto and their respective successors and assigns.

This Leak-Out Agreement may not be amended or modified except in writing signed by each of the parties hereto.

All questions concerning the construction, validity, enforcement and interpretation of this Leak-Out Agreement shall be governed by the terms of the Exchange Agreement.

Each party hereto acknowledges that, in view of the uniqueness of the transactions contemplated by this Leak-Out Agreement, the other party or parties hereto may not have an adequate remedy at law for money damages in the event that this Leak-Out Agreement has not been performed in accordance with its terms, and therefore agrees that such other party or parties shall be entitled to seek specific enforcement of the terms hereof in addition to any other remedy it may seek, at law or in equity.

The obligations of the Holder under this Leak-Out Agreement are several and not joint with the obligations of any other holder of securities issued upon exercise (other than pursuant to the terms of such securities in effect as of the date hereof and assuming, for such purpose, no amendment or waiver thereof except such amendments and waiver in effect prior to the date hereof) or exchange, as applicable, of any outstanding warrants to purchase Common Stock of the Company (each, an "Other Holder"), and the Holder shall not be responsible in any way for the performance of the obligations of any Other Holder under any other agreement (including, without limitation, any other leak-out agreement (each, an "Other Leak-Out Agreement"). Nothing contained herein or in this Leak-Out Agreement, and no action taken by the Holder pursuant hereto, shall be deemed to constitute the Holder and Other Holders as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Holder and the Other Holders are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by this Leak-Out Agreement and the Company acknowledges that the Holder and the Other Holders are not acting in concert or as a group with respect to such obligations or the transactions contemplated by this Leak-Out Agreement or any other agreement. The Company and the Holder confirm that the Holder has independently participated in the negotiation of the transactions contemplated hereby with the advice of its own counsel and advisors. The Holder shall be entitled to independently protect and enforce its rights, including, without limitation, the rights arising out of this Leak-Out Agreement, and it shall not be necessary for any Other Holder or any Prospectus Purchaser Other Holder to be joined as an additional party in any proceeding for such purpose.

The Company hereby represents and warrants as of the date hereof and covenants and agrees from and after the date hereof that it will enforce the provisions of each Other Leak-Out Agreement, if any, in accordance with its terms. If any party to any Other Leak-Out Agreement breaches any provision of such Other Leak-Out Agreement, the Company shall promptly use its best efforts to seek specific performance of the terms of such Other Leak-Out Agreement.

The Company hereby represents and warrants as of the date hereof and covenants and agrees from and after the date hereof that none of the terms offered to any Other Holder with respect to (x) any exchange of any of the \_\_\_\_\_ and \_\_\_\_\_ Warrants (as defined in the Warrant Exchange Agreement) into any other securities of the Company or (y) any restrictions on (or failure to restrict) the sale of any such securities (including, without limitation, any Other Leak-Out Agreement or the failure by the Company to obtain any Other Leak-Out Agreement with respect thereto) (each a "Settlement Document"), is or will be more favorable to such Other Holder or any Prospectus Purchaser Other Holder than those of the Holder and this Leak-Out Agreement (for the avoidance of doubt, a Leak Out Percentage (as defined in each Other Leak-Out Agreement) of an Other Holder that is the same as the February Leak-Out Percentage (as defined in each Other Leak-Out Agreement) of such Other Holder shall not be a more favorable term of such Other Leak-Out Agreement). If, and whenever on or after the date hereof, the Company enters into a Settlement Document with terms that are materially different from this Leak-Out Agreement, then (i) the Company shall provide notice thereof to the Holder promptly following the occurrence thereof and (ii) the terms and conditions of this Leak-Out Agreement shall be, without any further action by the Holder or the Company, automatically amended and modified in an economically and legally equivalent manner such that the Holder shall receive the benefit of the more favorable terms and/or conditions (as the case may be) set forth in such Settlement Document, provided that upon written notice to the Company at any time the Holder may elect not to accept the benefit of any such amended or modified term or condition, in which event the term or condition contained in this Leak-Out Agreement shall apply to the Holder as it was in effect immediately prior to such amendment or modification as if such amendment or modification never occurred with respect to the Holder. The provisions of this paragraph shall apply similarly and equally to each Settlement Document.

[The remainder of the page is intentionally left blank]

The parties hereto have executed this Leak-Out Agreement as of the date first set forth above.

Sincerely,

**DELCATH SYSTEMS, INC.**

By: \_\_\_\_\_  
Name:  
Title:

Agreed to and Acknowledged:

\_\_\_\_\_

By: \_\_\_\_\_  
Name:  
Title:

**GLOBAL SETTLEMENT AGREEMENT**

THIS GLOBAL SETTLEMENT AGREEMENT (the “Agreement”) is made as of April 18, 2019 (the “Effective Date”) by and among Delcath Systems, Inc. (“Plaintiff” or the “Company”), Iroquois Capital Investment Group, LLC (“Iroquois Capital”), Iroquois Master Fund Ltd. (“Iroquois Master”), and FirstFire Global Opportunities Fund LLC (“FirstFire” and with Iroquois Capital and Iroquois Master, “Defendants” each of which is a “Defendant” and with Plaintiff, the “Parties” each of which is a “Party”).

**RECITALS**

A. On or about February 9, 2018, Defendants and twelve other parties (the “Consenting Warrant Holders” and with Defendants, the “Warrant Holders”) purchased Series D Warrants to Purchase Two Shares of Common Stock (the “Warrants”) which Plaintiff issued pursuant to a prospectus and related documents filed with the United States Securities and Exchange Commission.

B. Plaintiff later identified what it has alleged is an erroneous cross-reference in the Warrants.

C. In late 2018, Plaintiff offered the Warrant Holders an opportunity to exchange their Warrants for shares of common stock in the Company pursuant to an exchange agreement (the “Exchange Agreement”).

D. As of March 26, 2019, eleven of the Consenting Warrant Holders had executed the Exchange Agreement.

E. On March 26, 2019, Plaintiff commenced an action against Defendants and the twelfth Consenting Warrant Holder in Supreme Court of the State of New York, New York County, captioned *Delcath Systems, Inc. v. Iroquois Capital Investment Group LLC, et al.*, Index No. 651749/2019 (the “Reformation Action”). The Reformation Action sought to reform the Warrants in the manner that Plaintiff contends is their intended meaning. The twelfth Consenting Warrant Holder subsequently executed the Exchange Agreement.

F. As of the date of this Agreement, Defendants are the only Warrant Holders who have not executed the Exchange Agreement and they are the only Defendants in the Reformation Action.

G. The Parties desire to resolve the Reformation Action without further litigation and, after arm’s length negotiations, have agreed to the settlement set forth in this Agreement.

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## SETTLEMENT TERMS

For good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties agree to the following terms:

### **1. Representations and Warranties of the Parties**

Each of the Parties represents and warrants as follows:

(a) such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all necessary power and authority to enter into this Agreement, to carry out the obligations it imposes and to consummate the transactions it requires to be consummated (the "Transactions");

(b) the execution, delivery and performance by such Party of its obligations hereunder and consummation by such Party of the Transactions have been duly authorized by all necessary actions on the part of such Party;

(c) this Agreement constitutes a legal, valid and binding obligation of such Party enforceable against such Party in accordance with its terms; and

(d) the execution, delivery and performance by such Party of its obligations hereunder will not be *ultra vires* or violate, conflict with or result in the breach of any provision of the organizational documents of such Party.

### **2. Settlement Terms**

In consideration of this Agreement:

(a) On the Effective Date, Defendants shall surrender the Warrants to the Company and shall thereupon waive all of the rights granted by or in connection with the Warrants;

(b) On the Effective Date, Defendants shall waive any and all rights under the Defendants' respective Stock Purchase Agreements dated as of February 9, 2018 with respect to participation in the Company's future common stock offerings;

(c) Within three business days of the Effective Date, Plaintiff shall pay Defendants' counsel one-fifth of the reasonable, documented, out-of-pocket fees, costs, and expenses Defendants' counsel incurred in connection with the Reformation Action and this Agreement, the total of which shall not exceed \$50,000.00 ("Defendants' Legal Fees");

(d) Plaintiff shall pay Defendants \$400,000.00 (the "Settlement Payment"); **provided, however**, that this payment will be made **only** if Plaintiff secures and closes financing in the form of a Private Investment in Public Equity or similar-type transaction ("PIPE Financing") such that Plaintiff can continue its operations without filing for bankruptcy protection; and **provided further**, that Plaintiff's failure to secure and close such PIPE Financing

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and make the Settlement Payment within five business days of securing and closing such PIPE Financing, shall void this Agreement in its entirety;<sup>1</sup>

(e) Contemporaneously with Plaintiff's payment of the Settlement Payment, Plaintiff shall pay Defendants' counsel the remaining eighty percent (80%) of Defendants' Legal Fees; and

(f) Plaintiff shall either withdraw the Reformation Action or file a notice of discontinuance of the Reformation Action, either as applicable, within five business days of making the Settlement Payment.

### **3. General Releases**

(a) As of the Effective Date, Plaintiff hereby forever releases (i) each of Defendants and (ii) each of their respective past and present parent companies, divisions, subsidiaries, affiliates, joint ventures, predecessors, successors, transferees, assigns, subrogees, insurers, co-insurers, reinsurers, representatives, agents, stockholders or owners of Defendants (collectively, the "Defendant Releasees"), from any and all claims, including, without limitation, defaults, obligations, rights, damages, causes of action, demands, suits, judgments, remedies, setoffs, recoupments, defenses, debts, and liabilities of any kind or nature whatsoever, under any legal theory, including under contract, tort, or otherwise, whether at law, in equity, or otherwise, whether known or unknown, matured or unmatured, fixed or contingent, liquidated or unliquidated, disputed or undisputed, asserted or unasserted, suspected or unsuspected, foreseen or unforeseen, direct or indirect, choate or inchoate, now existing or hereafter arising) (each a "Claim") that Plaintiff may now have, has ever had or may in the future have, against a Defendant Releasee arising prior to the Effective Date hereof.

(b) As of the Effective Date, each Defendant hereby forever releases (i) Plaintiff and (ii) its past and present parent companies, divisions, affiliates, joint ventures, predecessors, successors, transferees, assigns, subrogees, insurers, co-insurers, reinsurers, representatives, agents, stockholders or owners (collectively, the "Plaintiff Releasees"), from any Claim that any Defendant or any affiliate of any Defendant may now have, has ever had or may in the future have, against a Plaintiff Releasee arising prior to the Effective Date hereof.

(c) Notwithstanding the foregoing, no Party hereby releases claims arising out of, related to or in connection with (i) its rights or obligations under, or actions required by, this Agreement, or (ii) rights under or in connection with the Company's securities other than the Warrants.

### **4. Counterparts**

This Agreement may be executed in counterparts, each of which shall be an original and all which together shall constitute a single agreement.

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<sup>1</sup> For the avoidance of doubt, the Settlement Payment shall not be due and payable upon any bridge financings of up to and cumulatively including \$5.0 million.

**5. Amendments**

No amendment, modification or waiver in respect of this Agreement will be effective unless in writing (including writing evidenced by facsimile transmission or electronic transmission of a Portable Document Format file) and executed by each of the parties hereto.

**6. Severability**

If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced under any Law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect. Upon a determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties shall negotiate in good faith to modify this Agreement so as to effectuate the original intent of the parties as closely as possible so that the Transactions are consummated as originally contemplated to the greatest extent possible.

**7. Entire Agreement**

This Agreement sets forth the entire understanding and agreement between the parties as to the matters addressed herein and supersedes and replaces any prior understanding, agreement or statement of intent, written or oral.

**8. Binding Nature**

The terms and provisions of this Agreement shall be binding in all respects on, and shall inure to the benefit of, the Parties, their successors and assigns. No other person or entity shall have rights under this Agreement.

**9. Joint Drafting**

This Agreement is the product of arm's length negotiations between the Parties and any rule of construction that ambiguities are to be resolved against the drafting Party shall not apply in the interpretation of this Agreement.

**10. No Admissions**

This Agreement reflects a compromise of disputed claims and shall not be construed as an admission against any Party's interest and shall not be used as or deemed to be evidence of any liability by any Party in any proceeding before any court, except in a proceeding to enforce the terms of this Agreement.

**11. Governing Law**

Except as provided for herein, this Agreement shall be interpreted under and governed by the laws of the State of New York without giving effect to any conflicts of law provisions thereof that would make the law of any other jurisdiction applicable to this Agreement.

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IN WITNESS WHEREOF, Plaintiff and the Defendants each caused this instrument to be signed by their duly authorized representatives, as of the date first above written.

**DELCATH SYSTEMS, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**IROQUOIS CAPITAL INVESTMENT GROUP, LLC**

By: \_\_\_\_\_  
Name:  
Title:

**IROQUOIS MASTER FUND LTD.**

By: \_\_\_\_\_  
Name:  
Title:

**FIRSTFIRE GLOBAL OPPORTUNITIES FUND LLC**

By: \_\_\_\_\_  
Name:  
Title:

**SECURITIES PURCHASE AGREEMENT**

This Securities Purchase Agreement (this "Agreement") is dated as of April 18, 2019, by and among Delcath Systems, Inc., a Delaware corporation (the "Company"), and the purchasers identified on the signature pages hereto (each, a "Purchaser," or in the aggregate, the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), Regulation S and Rule 506(b) promulgated thereunder, the Company desires to sell, and the Purchasers desire to purchase from the Company, the Securities (as defined herein).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

**ARTICLE I.  
DEFINITIONS**

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement: (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Transaction Documents (as defined herein), and (b) the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"BHCA" shall have the meaning ascribed to such term in Section 3.1(l).

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

"Closing Date" means the Trading Day(s) on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto in connection with a Closing, and all conditions precedent to (i) the Purchaser's obligations to pay the Subscription Amount as to the Closing and (ii) the Company's obligations to deliver the Securities as to the Closing, in each case, have been satisfied or waived.

"Closing" means closing of the purchase and sale of the Securities pursuant to Section 2.2.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Disclosure Schedules” shall have the meaning ascribed to such term in Section 3.1.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(t).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exchange Transaction” shall have the meaning ascribed to such term in Section 4.15(b).

“Exempt Issuance” means the issuance of (a) shares of Common Stock, restricted stock units or options to employees, officers, directors, advisors or independent contractors of the Company pursuant to any stock or option plan duly adopted for such purpose, (b) shares of Common Stock, warrants or options to advisors or independent contractors of the Company for compensatory purposes, (c) securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date hereof, provided that such securities have not been amended since the date hereof to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, (d) securities issuable pursuant to any contractual anti-dilution, most favored nations or similar obligations of the Company in effect as of the date hereof, provided that such obligations have not been materially amended since the date of hereof, and (e) securities issued pursuant to acquisitions or any other strategic transactions approved by the Board of Directors, provided that any such issuance shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“Federal Reserve” shall have the meaning ascribed to such term in Section 3.1(ll).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Guarantors” mean collectively, the Subsidiaries of the Company who are party to the Subsidiary Guarantee.

“Indebtedness” means except for Permitted Indebtedness, (a) any liabilities for borrowed money or amounts owed in excess of \$100,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$100,000 due under leases required to be capitalized in accordance with GAAP.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(q).

“Intellectual Property Security Agreement” means that certain Intellectual Property Security Agreement required to be delivered pursuant to Section 2.3 of this Agreement, in the form attached hereto as Exhibit B.

“Liabilities” means all direct or indirect liabilities, Indebtedness and obligations of any kind of Company to the Purchaser, howsoever created, arising or evidenced, whether now existing or hereafter arising (including those acquired by assignment), absolute or contingent, due or to become due, primary or secondary, joint or several, whether existing or arising through discount, overdraft, purchase, direct loan, participation, operation of law, or otherwise, including, but not limited to, pursuant to the Note, this Agreement and/or any of the other Transaction Documents, all accrued but unpaid interest on the Note, any letter of credit, any standby letter of credit, and/or outside attorneys’ and paralegals’ fees or charges relating to the preparation of the Transaction Documents and the enforcement of the Purchaser’s rights, remedies and powers under this Agreement, the Note and/or the other Transaction Documents.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Maximum Rate” shall have the meaning ascribed to such term in Section 5.17.

“Money Laundering Laws” shall have the meaning ascribed to such term in Section 3.1(qq).

“Notes” means collectively, the 8% Senior Secured Promissory Notes issued by the Company to each Purchaser hereunder, each in the form of Exhibit A attached hereto.

“Off-balance Sheet Arrangement” shall have the meaning ascribed to such term in Section 3.1(pp).

“Permitted Indebtedness” means the letters of credit and secured accounts listed in Schedule 3.1(h).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Principal Amount” means, as to the Purchaser, the principal amount of the Notes set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto in United States Dollars.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.9.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rosalind Note” means the Note originally held by Rosalind Master Fund, L.P.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities” means the Notes to be issued to the Purchaser pursuant to this Agreement.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Security Agreement” means the Security Agreement dated on the date hereof by and among the Company, the Company’s Subsidiaries, and the Purchaser, as hereinafter amended and/or supplemented altogether with all exhibits, schedules and annexes to such Security Agreement, pursuant to which all Liabilities of the Company to the Purchaser under the Transaction Documents are secured by the Collateral (as defined in the Security Agreement), which security interest in the Collateral shall be perfected by the Purchaser’s UCC-1, filed with the Secretary of State of the State of Delaware, to the extent perfectable by the filing of a UCC-1 Financing Statement, or if applicable, a UCC-3 Financing Statement Amendment and such other documents and instruments related thereto, which Security Agreement is annexed hereto as Exhibit C.

“Shell Company” means an entity that fits within the definition of “shell company” under Section 12b-2 of the Exchange Act and Rule 144.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act.

“Subscription Amount” means, as to the Purchaser, the aggregate amount to be paid for the Notes purchased hereunder as specified below the Purchaser’s name on the signature page of this Agreement and next to the heading “Subscription Amount,” in United States dollars and in immediately available funds.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Subsidiary Guarantee” means the Subsidiary Guarantee, dated as of the date hereof, pursuant to which the Subsidiaries have jointly and severally agreed to guarantee and act as surety for the Company’s obligation to repay the Notes, in the form attached hereto as Exhibit D.

“Third Party Exchange Transfer” shall have the meaning ascribed to such term in Section 4.14(b).

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; OTC Markets or the OTC Bulletin Board (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Notes, the Security Agreement, the Intellectual Property Security Agreement, the Subsidiary Guarantee and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.14(a).

## **ARTICLE II. PURCHASE AND SALE**

2.1 Purchase. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company shall sell and issue to each Purchaser, and each Purchaser shall purchase, severally and not jointly, from the Company, Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto. The purchase of the Notes will be completed in a single tranche as provided herein.

2.2 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and each Purchaser agrees to purchase, the Subscription Amount of Notes as set forth on the signature page hereto executed by such Purchaser. At the Closing, each Purchaser shall deliver to the Company, via wire transfer to an account designated by the Company, immediately available funds equal to such Purchaser’s Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to

such Purchaser its Notes as set forth in Section 2.3(a), and the Company and such Purchaser shall deliver the other items set forth in Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4 for Closing, such Closing shall be undertaken remotely by electronic exchange of Closing documentation. There may be multiple closings so long as at each Closing the obligations under Section 2.3 are met.

### 2.3 Deliveries.

- (a) On or prior to the Closing Date (except as otherwise agreed by the Purchaser), the Company shall deliver or cause to be delivered to each Purchaser the following:
- (i) this Agreement duly executed by the Company;
  - (ii) the Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser's name in column (2) on the Schedule of Purchasers attached hereto, registered in the name of the Purchaser;
  - (iii) the Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Security Agreement);
  - (iv) the Intellectual Property Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Intellectual Property Security Agreement);
  - (v) the Subsidiary Guarantee, duly executed by the Company's Subsidiaries (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Subsidiary Guarantee);
  - (vi) [Reserved];
  - (vii) the opinion of Wexler Burkhart Hirschberg & Unger, LLP, the Company's counsel, dated as of the Closing Date;
  - (viii) [Reserved];
  - (ix) a certificate evidencing the Company's qualification as a foreign corporation and good standing issued by the Secretary of State (or comparable office) of each jurisdiction, if any, in which the Company conducts business and is required to so qualify, as of a date within ten (10) days of the Closing Date;
  - (x) a certificate executed by the Secretary of the Company and dated as of the Closing Date, as to (i) the resolutions, as adopted by the Board of Directors in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of this Agreement and the other Transaction Documents and the

issuance, offering and sale of the Securities and (B) the performance of the Company of its obligations under the Transaction Documents contemplated therein, (ii) referencing links to the Company's amended and restated certificate of incorporation, as amended, (iii) referencing links to the Company's amended and restated by-laws, each as in effect at the Closing and (iv) attaching a certificate of incumbency;

(xi) a certificate executed by the Secretary of the each Guarantor and dated as of the Closing Date, as to (i) the resolutions, as adopted by the board of directors of such Guarantor in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of Transaction Documents to which it is a party and (B) the performance of Guarantor of its obligations under the Transaction Documents to which it is a party contemplated therein, (ii) referencing links to Guarantor's constating documents and (iii) attaching a certificate of incumbency; and

(xii) such other documents, instruments or certificates relating to the transactions contemplated by this Agreement as such Purchaser or its counsel may reasonably request.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, as applicable, the following:

(i) this Agreement, duly executed by the Purchaser;

(ii) the Purchaser's Subscription Amount by wire transfer to the account specified in writing by the Company;

(iii) the Security Agreement, duly executed by the Purchaser; and

(iv) the Intellectual Property Security Agreement, duly executed by the Purchaser.

#### 2.4 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects as at Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed; and



(iii) the delivery by the Purchaser of the items set forth in Section 2.3(b) of this Agreement.

(b) The respective obligations of each Purchaser hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects when made as to the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.3(a) of this Agreement;

(iv) there is no existing Event of Default (as defined in the Notes) and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default;

(v) there is no breach of any obligations, covenants and agreements under the Transaction Documents and no existing event which, with the passage of time or the giving of notice, would constitute a breach under the Transaction Documents;

(vi) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;

(vii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of the Purchaser, and without regard to any factors unique to the Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing;

(viii) [reserved];

(ix) [reserved]; and

(x) any other conditions contained herein or the other Transaction Documents, including, without limitation those set forth in Section 2.3 herein.

2.5 Minimum and Maximum. Each Purchaser must purchase Securities for a minimum subscription amount of at least \$100,000. Provided, however, that if necessary to meet Company's existing obligations under rights of participation, the minimum subscription amount per party may be reduced pro rata to the extent necessary to enable all persons with such rights that desire to participate to so participate. The aggregate subscription amount for all securities to all Purchasers may not exceed \$4,000,000.

### **ARTICLE III. REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the disclosure schedules attached hereto (the "Disclosure Schedules"), which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company (which for purposes of this Section 3.1 means the Company and all of its Subsidiaries) hereby makes the following representations and warranties to each Purchaser as of the Closing Date:

(a) Subsidiaries. All of the direct and indirect Subsidiaries and parent entities of the Company are set forth on Schedule 3.1(a) hereto. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, other than as set forth on Schedule 3.1(a) hereto, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized and validly existing, and, other than as set forth on Schedule 3.1(b) hereto, the Company is in good standing, under the laws of the jurisdiction of its incorporation or organization, as applicable, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary or parent entity of the Company is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document; (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, its parent entities and the Subsidiaries, taken as a whole; or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not, except as set forth on Schedule 3.1(d): (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents; (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien (except Liens in favor of the Purchaser) upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected; or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to

Section 4.13 of this Agreement; (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Securities in the time and manner required thereby; and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the “Required Approvals”).

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization; Corporate Governance.

(i) The capitalization of the Company is as set forth on Schedule 3.1(g)(i), which Schedule 3.1(g)(i) shall also include (A) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof and (B) the number of authorized and reserved shares of capital stock of the Company. The Company has not issued capital stock since its most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i), except the issuance of shares of Common Stock to employees pursuant to the Company’s employee stock purchase plans and except pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents except as set forth on Schedule 3.1(g)(i). There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents except as set forth on Schedule 3.1(g)(i). The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities except as set forth on Schedule 3.1(g)(i). All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders’ agreements, voting agreements or other similar agreements with respect to the Company’s capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company’s stockholders.

(ii) The names and titles of each of the Company's principal officers, directors and beneficial holders of at least five percent (5%) of the outstanding shares of each class of the Company's capital stock on a fully diluted basis are as set forth on Schedule 3.1(g)(ii), which Schedule 3.1(g)(ii) shall also include each committee of directors as well as the names and titles of each director currently serving on each such committee.

(h) Indebtedness. Schedule 3.1(h) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Except as set forth on Schedule 3.1(h), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(i) SEC Reports; Financial Statements. Other than as set forth on Schedule 3.1(i) hereto, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports"). As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the Company's Annual Report on Form 10-K, including such latest audited financial statements, or in a subsequent SEC Report filed prior to the date hereof and except as set forth in Schedule 3.1(g), Schedule 3.1(m), and Schedule 3.1(j): (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect; (ii) the Company has not incurred any liabilities or obligations (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial

statements pursuant to GAAP or disclosed in filings made with the Commission; (iii) the Company has not altered its method of accounting; (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock; (v) the Company has not sold, assigned or transferred any other tangible assets or Intellectual Property Rights, or canceled any debts or claims, except in the ordinary course of business, (vi) the Company has not suffered any substantial loss contingencies or waived any rights of material value, whether or not in the ordinary course of business, or suffered the loss of any material amount of prospective business, (vii) the Company has not entered into any acquisition or financing transactions, whether or not in the ordinary course of business, other than with respect to the Transaction Documents and (v) the Company has not issued any equity securities to any officer, director or Affiliate, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties except as set forth in Schedule 3.1(k), or against or affecting the Company's current or former officers or directors in their capacity as such, before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company that is likely to lead to action that can reasonably be expected to result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary, except as set forth in Schedule 3.1(m): (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived); (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority; or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except as set forth in Schedule 3.1(q) and except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Material Agreements. Except for the Transaction Documents (with respect to clause (i) only) or as set forth on Schedule 3.1(p) hereto, or as would not be reasonably likely to have a Material Adverse Effect, (i) the Company and each of its Subsidiaries have performed all obligations required to be performed by them to date under any written or oral contract, instrument, agreement, commitment, obligation, plan or arrangement, filed or required to be filed with the Commission (the "Material Agreements"), (ii) neither the Company nor any of its Subsidiaries has received any notice of default under any Material Agreement and, (iii) to the best of the Company's knowledge, neither the Company nor any of its Subsidiaries is in default under any Material Agreement now in effect.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as presently conducted and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights except as disclosed in Schedule 3.1(q). The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.



(r) Transactions with Affiliates and Employees. Except as disclosed in Schedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from providing for the borrowing of money from or lending of money to, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for: (i) payment of salary or consulting fees for services rendered; (ii) reimbursement for expenses incurred on behalf of the Company; and (iii) other employee benefits.

(s) Payments of Cash. Except as disclosed on Schedule 3.1(s), neither the Company, its directors or officers, or any Affiliates or agents of the Company, have withdrawn or paid cash to any vendor in an aggregate amount that exceeds Five Thousand Dollars (\$5,000) for any purpose.

(t) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(u) Certain Fees. Other than as set forth on Schedule 3.1(u), no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiaries to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchaser shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(v) Private Placement. Assuming the accuracy of each Purchaser's representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

(w) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(x) Registration Rights. Other than as set forth on Schedule 3.1(x) and pursuant to this Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiaries.

(y) Listing and Maintenance Requirements; Trading Market Regulation. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC reports, the Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(z) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's amended and restated certificate of incorporation, as amended (or similar charter documents), or the laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchaser's ownership of the Securities.

(aa) Disclosure. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(bb) No Integrated Offering. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(cc) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchaser and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds; (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law; or (iv) violated in any material respect any provision of FCPA.

(ee) Accountants. The Company's accounting firm is set forth on Schedule 3.1(ee). To the knowledge and belief of the Company, such accounting firm is a registered public accounting firm as required by the Exchange Act.

(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

(gg) Acknowledgment Regarding Purchaser's Purchase of Securities. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by the Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Securities. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Securities.

(ii) Stock Option Plans. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their respective financial results or prospects.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the “BHCA”) and to regulation by the Board of Governors of the Federal Reserve System (the “Federal Reserve”). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Promotional Stock Activities. Neither the Company, its officers, its directors, nor any affiliates or agents of the Company have engaged in any stock promotional activity that could give rise to a complaint, inquiry, or trading suspension by the Commission alleging (i) a violation of the anti-fraud provisions of the federal securities laws, (ii) violations of the anti-touting provisions, (iii) improper “gun-jumping”; or (iv) promotion without proper disclosure of compensation.

(nn) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(oo) Seniority. As of the Closing Date, other than as set forth on Schedule 3.1(oo), no Indebtedness or other claim against the Company is senior to the Notes in right of payment, whether with respect to interest or upon liquidation or dissolution, or otherwise, other than indebtedness secured by purchase money security interests (which is senior only as to underlying assets covered thereby) and capital lease obligations (which is senior only as to the property covered thereby).

(pp) No “Off-balance Sheet Arrangements”. Other than as set forth in Schedule 3.1(pp), neither the Company nor any of its Affiliates is involved in any “Off-balance Sheet Arrangements”. For purposes hereof an “Off-balance Sheet Arrangement” means any transaction or contract to which an entity unconsolidated with the Company or any of its Affiliates is a party and under which either the Company or any such Affiliate has: (i) any obligation under a guarantee contract pursuant to which the Company or any of its Affiliates could be required to make payments to the guaranteed party, including any standby letter of credit, market value guarantee, performance guarantee, indemnification agreement, keep-well or other support agreement; (ii) any retained or contingent interest

in assets transferred to such unconsolidated entity that serves as credit, liquidity or market risk support to the entity in respect of such assets; (iii) any variable interest held in such unconsolidated entity where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with the Company of any of its Affiliates; and (iv) any liability or obligation of the same nature as those described in clauses (i) through (iii) of this sentence even if of a different name (whether absolute, accrued, contingent or otherwise) that would not be required to be reflected in the Company or any of its Affiliates' financial statements.

(qq) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(rr) Subsidiary Rights. The Company has the unrestricted right to vote, and (subject to limitations imposed by applicable law) to receive dividends and distributions on, all capital securities of each of its Subsidiaries as owned by the Company or any Subsidiary.

(ss) Shell Company Status. The Company has never been, and is not presently, an issuer identified as a Shell Company.

(tt) Investor Relations. Other than as set forth in Schedule 3.1(tt), the Company is not currently a party, nor does it intend to become a party, to any agreement pursuant to which the Company will receive investor relations services.

(uu) Full Disclosure. No representation or warranty by the Company in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to the Purchasers pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

(vv) No Bad Actor Disqualification Event. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d)(1) under the Securities Act (a "Disqualification Event") is applicable to Company or to Company's knowledge any of its Affiliates, except a Disqualification Event as to which Rule 506(d)(2)(iii) applies.

(ww) Company has not, and will not, engage in any directed selling efforts in the United States in respect of the Securities. Company is offering and selling the Securities only to non U.S. Persons, in compliance with the offering restriction requirements of Regulation S.

3.2 Representations and Warranties of the Purchaser. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by the Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. The Purchaser understands that the Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account (this representation and warranty not limiting the Purchaser's right to sell the Securities in compliance with applicable federal and state securities laws). The Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Securities, it was, and as of the date hereof it is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. The Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of the Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of the Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(g) Non U.S. Person. The Purchaser is not a "U.S. Person" as that term is defined in Regulation S under the Securities Act, and is not acquiring the Securities for the account or beneficial ownership of any U.S. Person.

(h) No Short Sales. Neither Purchaser nor any Affiliate of Purchaser (i) holds any short position in the Common Stock, (ii) has ever engaged in, directly or indirectly, any Short Sale of the Common Stock, or (iii) has ever engaged in, directly or indirectly, any hedging transaction with regard to the Common Stock.

(i) Not a Bad Actor. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d)(1) under the Securities Act is applicable to the Purchaser or any of its Affiliates. The Purchaser is not now, and has never been, subject to any final cease and desist order or any penalty from the Commission or any court of competent jurisdiction for any violation of any provision of the Securities Act or the Exchange Act, or any of the regulations promulgated thereunder.

(j) Not an Affiliate. The Purchaser is not now, and has never been, an Affiliate of the Company or any other Purchaser. The Purchaser is not now, and has never been, part of any group of Persons that would be required under Section 13(d) of the Exchange Act, or the rules and regulations promulgated thereunder, to file a statement on Schedule 13D or Schedule 13G with regard to the Company.

The Company acknowledges and agrees that the representations contained in Section 3.2 shall not modify, amend or affect the Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.



**ARTICLE IV.**  
**OTHER AGREEMENTS OF THE PARTIES**

4.1 Transfer Restrictions.

(a) The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, at the Company's sole expense in the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchaser agrees to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON REGULATION S OR AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO REGULATION S OR AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

The Company acknowledges and agrees that the Purchaser may from time to time pledge, pursuant to a bona fide margin agreement with a registered broker-dealer, or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement, the Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the Company's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities.

4.2 [Reserved].

4.3 [Reserved].

4.4 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.5 [Reserved].

4.6 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an “acquiring person” or such similar term under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchaser.

4.7 [Reserved].

4.8 Use of Proceeds. The Company shall use the net proceeds as set forth in Schedule 4.8.

4.9 Indemnification of Purchaser. Subject to the provisions of this Section 4.9, the Company will indemnify and hold the Purchaser and its directors, officers, managers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, managers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a “Purchaser Party”) harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys’ fees and costs of investigation that any the Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based in whole or in part upon a breach of the Purchaser Party’s representations, warranties or covenants under the Transaction Documents or any agreements or understandings the Purchaser Party may

have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by the Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of the Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (x) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (y) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnification contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 [Reserved].

4.11 Certain Transactions. The Purchaser covenants and agrees that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any Short Sales of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Company's Common Stock) during the period commencing with the execution of this Agreement and ending on the earlier of the Maturity Date (as defined in the Notes) of the Notes or the full repayment of the Notes; provided that this provision shall not operate to restrict a Purchaser's trading under any prior securities purchase agreement containing contractual rights that explicitly protects such trading in respect of the previously issued securities.

4.12 Securities Laws Disclosure; Publicity. The Company and the Purchaser shall consult with each other in issuing any public disclosure with respect to the transactions contemplated hereby, and neither the Company nor the Purchaser shall issue any such public disclosure nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or rules of the principal Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not

publicly disclose the name of the Purchaser, or include the name of the Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of the Purchaser, except: (a) as required by federal securities law in connection with any registration statement contemplated by this Agreement and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchaser with prior notice of such disclosure permitted under this clause (b).

4.13 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchaser at the Closing under applicable securities or “Blue Sky” laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

4.14 Subsequent Equity Sales.

(a) For so long as any of the Notes remain outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price.

(b) For as long as any of the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will (without the prior written consent of the Purchaser), directly or indirectly: (a) solicit, initiate, encourage or accept any other inquiries, proposals or offers from any Person relating to any exchange (i) of any security of the Company or any of its Subsidiaries for any other security of the Company or any of its Subsidiaries, except to the extent (x) consummated pursuant to the terms of Common Share Equivalents of the Company as in effect as of the date hereof and disclosed in filings with the Commission prior to the date hereof (without giving effect to any amendment, modification, change or waiver of any terms thereof occurring on or after the date hereof or not disclosed in a filing by the Company with the Commission prior to the date hereof) or (ii) of any indebtedness or other securities of, or claim against, the Company or any of its Subsidiaries pursuant to a registration statement filed with the Commission or relying on any exemption under the Securities Act (including, without

limitation, Section 3(a)(10) of the Securities Act (any such transaction described in clauses (i) or (ii), an “Exchange Transaction”); (b) enter into, effect, alter, amend, announce or recommend to its stockholders any Exchange Transaction with any Person; or (c) participate in any discussions, conversations, negotiations or other communications with any Person regarding any Exchange Transaction, or furnish to any Person any information with respect to any Exchange Transaction, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to seek an Exchange Transaction involving the Company or any of its Subsidiaries. For as long as the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will, directly or indirectly, cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to effect any acquisition of securities or indebtedness of, or claim against, the Company by such Person from an existing holder of such securities, indebtedness or claim in connection with a proposed exchange of such securities or indebtedness of, or claim against, the Company (whether pursuant to Section 3(a)(9) or 3(a)(10) of the Securities Act or otherwise) (a “Third Party Exchange Transfer”). The Company, its affiliates and Subsidiaries, and each of its and their respective officers, employees, directors, agents or other representatives shall immediately cease and cause to be terminated all existing discussions, conversations, negotiations and other communications with any Persons with respect to any of the foregoing. For all purposes of this Agreement, violations of the restrictions set forth in this Section 4.14 by any Subsidiary or affiliate of the Company, or any officer, employee, director, agent or other representative of the Company or any of its Subsidiaries or affiliates shall be deemed a direct breach of this Section 4.14 by the Company.

(c) From the date hereof until sixty (60) calendar days after the Closing Date, neither the Company nor any Subsidiary shall, directly or indirectly, except with respect to the proposed \$20,000,000 private investment in public equities contemplated to be completed by May 31, 2019, and as otherwise permitted under this Agreement, issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any “equity security” (as that term is defined under Rule 405 promulgated under the Securities Act), any Common Shares or Common Share Equivalents, any debt securities, any preferred stock or any purchase rights) or otherwise amend, modify, waiver or alter any terms of conditions of any Common Share Equivalents outstanding as of the date hereof to decrease the exercise, conversion and/or exchange price, as applicable, thereunder or otherwise increase the aggregate number of Common Shares issuable in connection therewith.

(d) The Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding the foregoing, this Section 4.14 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.15. **Regulation S Compliance.** Each Purchaser agrees that, during the six (6) months following the Closing, it shall not engage in any transaction involving any securities of the Company that would be prohibited or restricted by, or would otherwise render unavailable any applicable safe harbor provided by Regulation S.

## **ARTICLE V. MISCELLANEOUS**

5.1 **Termination.** This Agreement may be terminated by the Purchaser, as to the Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before April 23, 2019; provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 **Fees and Expenses.** The Company has agreed to bear all fees, disbursements, and expenses in connection with the transactions contemplated herein, including, without limitation, the Company's legal and accounting fees and disbursements, the costs incident to the preparation, printing and distribution of any registration statement, filing fees, UCC fees, and costs associated with the Intellectual Property Security Agreement. The Company shall pay all stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers in connection with the transactions contemplated hereby.

5.3 **Entire Agreement.** The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties hereto acknowledge have been merged into such documents, exhibits and schedules.

5.4 **Notices.** Any and all notices or other communications or deliveries to be provided by the Purchaser hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, New York 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Purchaser delivered in accordance with this Section 5.4. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service addressed to each Purchaser at the email address, facsimile number, or address of the Purchaser appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Purchaser. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers holding at least 50.1% in interest of the Notes, including the holder of the Rosalind Note, then outstanding or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 No Assignment. No party may assign this Agreement or any rights or obligations hereunder.

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Sections 4.9 and 5.5.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight

delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever the Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then the Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.



5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to the Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Usury. To the extent it may lawful do so, the Company hereby agrees not to insist upon or plead or in any manner whatsoever claim, and will resist any and all efforts to be compelled to take the benefit or advantage of, usury laws wherever enacted, now or at any time hereafter in force, in connection with any claim, action or proceeding that may be brought by the Purchaser in order to enforce any right or remedy under any Transaction Document. Notwithstanding any provision to the contrary contained in any Transaction Document, it is expressly agreed and provided that the total liability of the Company under the Transaction Documents for payments in the nature of interest shall not exceed the maximum lawful rate authorized under applicable law (the "Maximum Rate"), and, without limiting the foregoing, in no event shall any rate of interest or default interest, or both of them, when aggregated with any other sums in the nature of interest that the Company may be obligated to pay under the Transaction Documents exceed such Maximum Rate. It is agreed that if the maximum contract rate of interest allowed by law and applicable to the Transaction Documents is increased or decreased by statute or any official governmental action subsequent to the date hereof, the new maximum contract rate of interest allowed by law will be the Maximum Rate applicable to the Transaction Documents from the effective date thereof forward, unless such application is precluded by applicable law. If under any circumstances whatsoever, interest in excess of the Maximum Rate is paid by the Company to the Purchaser with respect to indebtedness evidenced by the Transaction Documents, such excess shall be applied by the Purchaser to the unpaid principal balance of any such indebtedness or be refunded to the Company, the manner of handling such excess to be at the Purchaser's election.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been cancelled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL.** **IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

*[Signature Pages Follow]*

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**DELCATH SYSTEMS, INC.**

Address for Notice:

By: \_\_\_\_\_

Name:

Title:

With a copy to (which shall not constitute notice):

Wexler Burkhardt Hirschberg & Unger, LLP

1633 Broadway

Suite 22C

New York, New York 10019

Attention: Barbra Keck

E-Mail: [bkeck@delcath.com](mailto:bkeck@delcath.com)

377 Oak Street

Concourse Level

Garden City, NY 11530

Attention: Jolie Kahn

e-mail: [jkahn@WBHULAW.COM](mailto:jkahn@WBHULAW.COM)

**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]**

**[PURCHASER SIGNATURE PAGES TO DELCATH SYSTEMS, INC. SECURITIES PURCHASE AGREEMENT]**

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: Rosalind Master Fund, LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:

\_\_\_\_\_

Title of Authorized Signatory:

\_\_\_\_\_

Email Address of Authorized Signatory:

\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount: \$180,000

EIN Number (if applicable):

\_\_\_\_\_

**SCHEDULE OF PURCHASERS**

<b>(1) Purchaser</b>	<b>(2) Principal Amount of Notes</b>	<b>(3) Subscription Amount</b>
Rosalind Master Fund, LP	180,000	180,000
	36	

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**EXHIBIT A**

**Form of Senior Secured Promissory Notes**

**EXHIBIT B**

**Form of Intellectual Property Security Agreement**

**EXHIBIT C**

**Form of Security Agreement**



**EXHIBIT D**

**Form of Subsidiary Guarantee**

**DISCLOSURE SCHEDULES TO THE  
SECURITIES PURCHASE AGREEMENT**

**BY AND AMONG DELCATH SYSTEMS, INC. AND EACH OF THE PURCHASERS SIGNATORY THERETO**

**DATED April 18, 2019**

These Sections (these “**Sections**”) of this Disclosure Schedule are numbered to correspond to the corresponding sections of the Securities Purchase Agreement (the “**Agreement**”). These Sections have been prepared in accordance with, and subject to, the following terms and conditions:

- (a) To the extent a Section is intended to qualify a representation or warranty of the Company contained in the Article III of the Agreement, the information and disclosures contained in such Section are intended only to qualify and limit such representation or warranty and not in any way expand the scope or effect of such representation or warranty.
- (b) The disclosure of any item in any Section of this Disclosure Schedule will constitute disclosure for purposes of another Section if it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other Sections or Sub-Sections.
- (c) Inclusion of any item in a Section of this Disclosure Schedule does not constitute a determination by the Company that such item is material and shall not be deemed to establish a standard or materiality. No disclosure in any Section of this Disclosure Schedule relating to any possible breach or violation of any agreement, law or any potential adverse contingency shall be construed as an admission or indication that any such breach or violation exists or has actually occurred or that such adverse contingency will actually occur.
- (d) Any capitalized terms not defined in this Disclosure Schedule shall have the meanings assigned thereto in the Agreement. Any section headings or titles used herein are included for convenience only and shall not be considered as representations or warranties as to the type, character or content of the matters referred to thereunder.

**SUBSIDIARIES OF THE COMPANY**

1. Delcath Holdings Limited
2. Delcath Systems Limited
3. Delcath Systems UK Limited
4. Delcath Systems GmbH
5. Delcath Systems B.V.

**Organization and Qualification**

The Company is not in good standing in the State of Delaware as a result of its inability to pay the franchise taxes due in March 2019.

The Company is not in good standing in the State of New York as a result of its inability to pay taxes due in March 2019.

Conflicts

None.

Capitalization

- A. Shares beneficially owned by Affiliates: 1,284,329  
 B. 11.8 million shares issued since most recent periodic report

## Rights of Participation:

September 2017 Hudson Bay and Alto  
 February 2018: Registered Direct Investors  
 June 2018: Discover Fund

## Delcath Systems, Inc.

Capitalization table as of April 16, 2019

	<u>Authorized</u>	<u>Issued</u>	<u>Treasury</u>	<u>Outstanding</u>
Preferred Shares	10,000,000	-	-	-
Common Shares	1,000,000,000	17,464,807	-	17,464,807
Fully diluted common shares:				
Feb 2015 Warrants (\$0.01; exp 2/2020)				9
July 2015 Warrants (\$0.01; exp 7/2020)				9
Oct 2016 Warrants (\$0.01; exp 10/2021)				11
Feb 2018 Warrants (\$10.00; exp 2/2024)				189,000
Pre-funded Warrants (Discover Fund; \$0.01, exp through 6/2024)				16,615,317
June 2018 Warrants (Discover Fund, \$4.00; exp 6/2023)				1,116,256
Pre-funded Warrants (Discover Fund; \$0.01; exp through 7/2024)				12,981,926
July 2018 Warrants (Discover Fund, \$4.00 exp 7/2023)				785,737
Pre-funded Warrants (Discover Fund; \$0.01, exp through 8/2024)				23,777,381
August 2018 Warrants (Discover Fund, \$1.75; exp 8/2023)				2,021,410
Pre-funded Warrants (Bigger; \$0.01, exp through 9/2024)				830,854
Sept 2018 Warrants (Bigger, \$1.75; exp 9/2023)				279,506
Options				1,250,000
<b>Total shares reserved for warrants and options</b>				<u>59,847,416</u>
<b>Total shares issued and reserved:</b>				<u>77,312,223</u>
<b>Total shares available to issue:</b>				<u><u>922,687,777</u></u>

**Corporate Governance of Delcath Systems, Inc.**

Roger Stoll, Ph.D., Chairman

William Rueckert

Dr. Marco Taglietti

Dr. Jennifer Simpson

Audit Committee – William Rueckert, Chair; Roger Stoll

Compensation Committee – Marco Taglietti, Chair; William Rueckert

Nominating and Corp. Governance Committee – Roger Stoll, Chair; William Rueckert; Marco Taglietti

**Indebtedness**

1. Letter of credit issued by Silicon Valley Bank to Kasowitz, Benson, Torres and Friedman LLP with face amount of \$130,663.00.
2. Letter of credit issued by Silicon Valley Bank to SLG 810 7th Avenue Lessee LLC with face amount of \$881,297.08.
3. Indebtedness in a maximum amount of \$75,000 owed to Silicon Valley Bank under corporate credit card services agreement.
4. Indebtedness between Delcath Systems, Inc. and Delcath Holdings Limited pursuant to a License and Agreement to Share Intangible Development Costs dated as of January 1, 2012.
5. Indebtedness of \$5,478,559 between Delcath Systems, Inc. and Discover Growth Fund and Discover Growth Fund, LLC signatory to Securities Purchase Agreements dated as of June 4, 2018; July 20, 2018; August 29, 2018; and a Note Purchase and Exchange Agreement dated March 29, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
6. Indebtedness of \$469,975 between Delcath Systems, Inc. and the institutional investors signatory to Securities Purchase Agreements dated as of September 21, 2018 and the 8% Senior Secured Convertible Promissory Notes issued pursuant thereto.

**Existing Liens**

1. Liens of Silicon Valley Bank on account nos. 3301246486 and 3301264690, respectively, securing the letters of credit described in numbers 1 and 2 above.
2. Lien of Silicon Valley Bank account no. 3301464115 securing the Indebtedness described in number 3 above.
3. Lien of the institutional investor securing the Obligations described in numbers 5 and 6 above.



**SEC Reports; Financial Statements**

The Company has not timely filed its Annual Report on Form 10-K for the year ended December 31, 2018.

**Material Changes; Undisclosed Events, Liabilities or Developments**

See Schedule 3.1(m).

**Litigation**

1. In March 2019, the Company sued two affiliated Iroquois Funds and FirstFire seeking declaratory judgment, among other remedies, that the February 2018 warrants issued to them are deemed to not including an “exploding” antidilution feature upon a down round financing. The suit was filed in New York State Supreme Court in NY County, NY.

See Schedule 3.1(m) below for any potential claims.

**Compliance**

UBC Demand Letter for \$2,106,116.00.

Payables to Roth Capital in the amount of \$552,642.60.

Notice of Default from Discover Growth Fund and Discover Growth Fund, LLC in respect of the Indebtedness listed in paragraph 5 of Schedule 3.1(h).

Title to Assets

See Schedule 3.1(h).

Material Agreements

See Schedule 3.1(m).

**Intellectual Property**

None.

**Transactions with Affiliates and Employees**

Herein below are all back salaries and unreimbursed employee expenses through April 15, 2019:

Jennifer Simpson	\$	862,376
Barbra Keck	\$	536,181
John Purpura	\$	553,491
All other employees	\$	335,670
	\$	2,287,718



Cash Payments

None.

**Certain Fees**

Fees to Roth Capital Partners, LLC under waiver letter with Roth Capital Partners, LLC

Fees to Think Equity under Engagement Letter

**Registration Rights**

Warrants issued in February 2018

September 21, 2018 Securities Purchase Agreement

Accountants

Marcum LLP

Grant Thornton LLP (with respect to 2015, 2016 and 2017 audited financials only)

Seniority

See Schedule 3.1(h).

Off-balance Sheet Arrangements

None.

**Investor Relations**

Use of Proceeds

General working capital purposes.



## SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this “Agreement”) is dated as of April 26, 2019, by and among Delcath Systems, Inc., a Delaware corporation (the “Company”), and the purchasers identified on the signature pages hereto (each, a “Purchaser,” or in the aggregate, the “Purchasers”).

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), Regulation S and Rule 506(b) promulgated thereunder, the Company desires to sell, and the Purchasers desire to purchase from the Company, the Securities (as defined herein).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

### ARTICLE I. DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement: (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Transaction Documents (as defined herein), and (b) the following terms have the meanings set forth in this Section 1.1:

“Action” shall have the meaning ascribed to such term in Section 3.1(k).

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“BHCA” shall have the meaning ascribed to such term in Section 3.1(l).

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

“Closing Date” means the Trading Day(s) on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto in connection with a Closing, and all conditions precedent to (i) the Purchaser’s obligations to pay the Subscription Amount as to the Closing and (ii) the Company’s obligations to deliver the Securities as to the Closing, in each case, have been satisfied or waived.

“Closing” means closing of the purchase and sale of the Securities pursuant to Section 2.2.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Disclosure Schedules” shall have the meaning ascribed to such term in Section 3.1.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(t).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exchange Transaction” shall have the meaning ascribed to such term in Section 4.15(b).

“Exempt Issuance” means the issuance of (a) shares of Common Stock, restricted stock units or options to employees, officers, directors, advisors or independent contractors of the Company pursuant to any stock or option plan duly adopted for such purpose, (b) shares of Common Stock, warrants or options to advisors or independent contractors of the Company for compensatory purposes, (c) securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date hereof, provided that such securities have not been amended since the date hereof to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, (d) securities issuable pursuant to any contractual anti-dilution, most favored nations or similar obligations of the Company in effect as of the date hereof, provided that such obligations have not been materially amended since the date of hereof, and (e) securities issued pursuant to acquisitions or any other strategic transactions approved by the Board of Directors, provided that any such issuance shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“Federal Reserve” shall have the meaning ascribed to such term in Section 3.1(ll).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Guarantors” mean collectively, the Subsidiaries of the Company who are party to the Subsidiary Guarantee.

“Indebtedness” means except for Permitted Indebtedness, (a) any liabilities for borrowed money or amounts owed in excess of \$100,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$100,000 due under leases required to be capitalized in accordance with GAAP.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(q).

“Intellectual Property Security Agreement” means that certain Intellectual Property Security Agreement required to be delivered pursuant to Section 2.3 of this Agreement, in the form attached hereto as Exhibit B.

“Liabilities” means all direct or indirect liabilities, Indebtedness and obligations of any kind of Company to the Purchaser, howsoever created, arising or evidenced, whether now existing or hereafter arising (including those acquired by assignment), absolute or contingent, due or to become due, primary or secondary, joint or several, whether existing or arising through discount, overdraft, purchase, direct loan, participation, operation of law, or otherwise, including, but not limited to, pursuant to the Note, this Agreement and/or any of the other Transaction Documents, all accrued but unpaid interest on the Note, any letter of credit, any standby letter of credit, and/or outside attorneys’ and paralegals’ fees or charges relating to the preparation of the Transaction Documents and the enforcement of the Purchaser’s rights, remedies and powers under this Agreement, the Note and/or the other Transaction Documents.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Maximum Rate” shall have the meaning ascribed to such term in Section 5.17.

“Money Laundering Laws” shall have the meaning ascribed to such term in Section 3.1(qq).

“Notes” means collectively, the 8% Senior Secured Promissory Notes issued by the Company to each Purchaser hereunder, each in the form of Exhibit A attached hereto.

“Off-balance Sheet Arrangement” shall have the meaning ascribed to such term in Section 3.1(pp).

“Permitted Indebtedness” means the letters of credit and secured accounts listed in Schedule 3.1(h).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Principal Amount” means, as to the Purchaser, the principal amount of the Notes set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto in United States Dollars.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.9.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rosalind Notes” means the Notes originally held by Rosalind Opportunities Fund I LP and Rosalind Master Fund LP.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities” means the Notes to be issued to the Purchaser pursuant to this Agreement.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Security Agreement” means the Security Agreement dated on the date hereof by and among the Company, the Company’s Subsidiaries, and the Purchaser, as hereinafter amended and/or supplemented altogether with all exhibits, schedules and annexes to such Security Agreement, pursuant to which all Liabilities of the Company to the Purchaser under the Transaction Documents are secured by the Collateral (as defined in the Security Agreement), which security interest in the Collateral shall be perfected by the Purchaser’s UCC-1, filed with the Secretary of State of the State of Delaware, to the extent perfectable by the filing of a UCC-1 Financing Statement, or if applicable, a UCC-3 Financing Statement Amendment and such other documents and instruments related thereto, which Security Agreement is annexed hereto as Exhibit C.

“Shell Company” means an entity that fits within the definition of “shell company” under Section 12b-2 of the Exchange Act and Rule 144.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act.

“Subscription Amount” means, as to the Purchaser, the aggregate amount to be paid for the Notes purchased hereunder as specified below the Purchaser’s name on the signature page of this Agreement and next to the heading “Subscription Amount,” in United States dollars and in immediately available funds.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Subsidiary Guarantee” means the Subsidiary Guarantee, dated as of the date hereof, pursuant to which the Subsidiaries have jointly and severally agreed to guarantee and act as surety for the Company’s obligation to repay the Notes, in the form attached hereto as Exhibit D.

“Third Party Exchange Transfer” shall have the meaning ascribed to such term in Section 4.14(b).

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; OTC Markets or the OTC Bulletin Board (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Notes, the Security Agreement, the Intellectual Property Security Agreement, the Subsidiary Guarantee and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.14(a).

## **ARTICLE II. PURCHASE AND SALE**

2.1 Purchase. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company shall sell and issue to each Purchaser, and each Purchaser shall purchase, severally and not jointly, from the Company, Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto. The purchase of the Notes will be completed in a single tranche as provided herein.

2.2 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and each Purchaser agrees to purchase, the Subscription Amount of Notes as set forth on the signature page hereto executed by such Purchaser. At the Closing, each Purchaser shall deliver to the Company, via wire transfer to an account designated by the Company, immediately available funds equal to such Purchaser’s Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to such Purchaser its Notes as set forth in Section 2.3(a), and the Company and such Purchaser shall deliver the other items set forth in Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4 for Closing, such Closing shall be undertaken remotely by electronic exchange of Closing documentation. There may be multiple closings so long as at each Closing the obligations under Section 2.3 are met.

Deliveries.

(a) On or prior to the Closing Date (except as otherwise agreed by the Purchaser), the Company shall deliver or cause to be delivered to each Purchaser the following:

- (i) this Agreement duly executed by the Company;
- (ii) the Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser's name in column (2) on the Schedule of Purchasers attached hereto, registered in the name of the Purchaser;
- (iii) the Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Security Agreement);
- (iv) the Intellectual Property Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Intellectual Property Security Agreement);
- (v) the Subsidiary Guarantee, duly executed by the Company's Subsidiaries (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Subsidiary Guarantee);
- (vi) [Reserved];
- (vii) the opinion of Wexler Burkhart Hirschberg & Unger, LLP, the Company's counsel, dated as of the Closing Date;
- (viii) [Reserved];
- (ix) a certificate evidencing the Company's qualification as a foreign corporation and good standing issued by the Secretary of State (or comparable office) of each jurisdiction, if any, in which the Company conducts business and is required to so qualify, as of a date within ten (10) days of the Closing Date;
- (x) a certificate executed by the Secretary of the Company and dated as of the Closing Date, as to (i) the resolutions, as adopted by the Board of Directors in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of this Agreement and the other Transaction Documents and the issuance, offering and sale of the Securities and (B) the performance of the Company of its obligations under the Transaction Documents contemplated therein, (ii) referencing links to the Company's amended and restated certificate of incorporation, as amended, (iii) referencing links to the Company's amended and restated by-laws, each as in effect at the Closing and (iv) attaching a certificate of incumbency;

(xi) a certificate executed by the Secretary of the each Guarantor and dated as of the Closing Date, as to (i) the resolutions, as adopted by the board of directors of such Guarantor in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of Transaction Documents to which it is a party and (B) the performance of Guarantor of its obligations under the Transaction Documents to which it is a party contemplated therein, (ii) referencing links to Guarantor's constating documents and (iii) attaching a certificate of incumbency; and

(xii) such other documents, instruments or certificates relating to the transactions contemplated by this Agreement as such Purchaser or its counsel may reasonably request.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, as applicable, the following:

(i) this Agreement, duly executed by the Purchaser;

(ii) the Purchaser's Subscription Amount by wire transfer to the account specified in writing by the Company;

(iii) the Security Agreement, duly executed by the Purchaser; and

(iv) the Intellectual Property Security Agreement, duly executed by the Purchaser.

#### 2.4 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects as at Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by the Purchaser of the items set forth in Section 2.3(b) of this Agreement.

(b) The respective obligations of each Purchaser hereunder in connection with the Closing are subject to the following conditions being met:

- (i) the accuracy in all material respects when made as to the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);
- (ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;
- (iii) the delivery by the Company of the items set forth in Section 2.3(a) of this Agreement;
- (iv) there is no existing Event of Default (as defined in the Notes) and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default;
- (v) there is no breach of any obligations, covenants and agreements under the Transaction Documents and no existing event which, with the passage of time or the giving of notice, would constitute a breach under the Transaction Documents;
- (vi) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;
- (vii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of the Purchaser, and without regard to any factors unique to the Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing;
- (viii) [reserved];
- (ix) [reserved]; and
- (x) any other conditions contained herein or the other Transaction Documents, including, without limitation those set forth in Section 2.3 herein.

2.5 Minimum and Maximum. Each Purchaser must purchase Securities for a minimum subscription amount of at least \$100,000. Provided, however, that if necessary to meet Company's existing obligations under rights of participation, the minimum subscription amount per party may be reduced pro rata to the extent necessary to enable all persons with such rights that desire to participate to so participate. The aggregate subscription amount for all securities to all Purchasers may not exceed \$4,000,000.



**ARTICLE III.  
REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the disclosure schedules attached hereto (the “Disclosure Schedules”), which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company (which for purposes of this Section 3.1 means the Company and all of its Subsidiaries) hereby makes the following representations and warranties to each Purchaser as of the Closing Date:

(a) Subsidiaries. All of the direct and indirect Subsidiaries and parent entities of the Company are set forth on Schedule 3.1(a) hereto. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, other than as set forth on Schedule 3.1(a) hereto, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized and validly existing, and, other than as set forth on Schedule 3.1(b) hereto, the Company is in good standing, under the laws of the jurisdiction of its incorporation or organization, as applicable, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary or parent entity of the Company is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document; (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, its parent entities and the Subsidiaries, taken as a whole; or (iii) a material adverse effect on the Company’s ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a “Material Adverse Effect”) and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the

Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not, except as set forth on Schedule 3.1(d): (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents; (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien (except Liens in favor of the Purchaser) upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected; or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.13 of this Agreement; (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Securities in the time and manner required thereby; and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization; Corporate Governance.

(i) The capitalization of the Company is as set forth on Schedule 3.1(g)(i), which Schedule 3.1(g)(i) shall also include (A) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof and (B) the number of authorized and reserved shares of capital stock of the Company. The Company has not issued capital stock since its most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i), except the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and except pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents except as set forth on Schedule 3.1(g)(i). There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents except as set forth on Schedule 3.1(g)(i). The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities except as set forth on Schedule 3.1(g)(i). All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders' agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(ii) The names and titles of each of the Company's principal officers, directors and beneficial holders of at least five percent (5%) of the outstanding shares of each class of the Company's capital stock on a fully diluted basis are as set forth on Schedule 3.1(g)(ii), which Schedule 3.1(g)(ii) shall also include each committee of directors as well as the names and titles of each director currently serving on each such committee.

(h) Indebtedness. Schedule 3.1(h) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Except as set forth on Schedule 3.1(h), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(i) SEC Reports; Financial Statements. Other than as set forth on Schedule 3.1(i) hereto, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”). As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the Company’s Annual Report on Form 10-K, including such latest audited financial statements, or in a subsequent SEC Report filed prior to the date hereof and except as set forth in Schedule 3.1(g), Schedule 3.1(m), and Schedule 3.1(j): (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect; (ii) the Company has not incurred any liabilities or obligations (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in filings made with the Commission; (iii) the Company has not altered its method of accounting; (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock; (v) the Company has not sold, assigned or transferred any other tangible assets or Intellectual Property Rights, or canceled any debts or claims, except in the ordinary course of business, (vi) the Company

has not suffered any substantial loss contingencies or waived any rights of material value, whether or not in the ordinary course of business, or suffered the loss of any material amount of prospective business, (vii) the Company has not entered into any acquisition or financing transactions, whether or not in the ordinary course of business, other than with respect to the Transaction Documents and (v) the Company has not issued any equity securities to any officer, director or Affiliate, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties except as set forth in Schedule 3.1(k), or against or affecting the Company's current or former officers or directors in their capacity as such, before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company that is likely to lead to action that can reasonably be expected to result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of

each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary, except as set forth in Schedule 3.1(m): (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived); (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority; or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except as set forth in Schedule 3.1(o) and except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Material Agreements. Except for the Transaction Documents (with respect to clause (i) only) or as set forth on Schedule 3.1(p) hereto, or as would not be reasonably likely to have a Material Adverse Effect, (i) the Company and each of its Subsidiaries have performed all obligations required to be performed by them to date under any written or oral contract, instrument, agreement, commitment, obligation, plan or arrangement, filed or required to be filed with the Commission (the "Material Agreements"), (ii) neither the Company nor any of its Subsidiaries has received any notice of default under any Material Agreement and, (iii) to the best of the Company's knowledge, neither the Company nor any of its Subsidiaries is in default under any Material Agreement now in effect.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as presently conducted and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights except as disclosed in Schedule 3.1(q). The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) Transactions with Affiliates and Employees. Except as disclosed in Schedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from providing for the borrowing of money from or lending of money to, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for: (i) payment of salary or consulting fees for services rendered; (ii) reimbursement for expenses incurred on behalf of the Company; and (iii) other employee benefits.

(s) Payments of Cash. Except as disclosed on Schedule 3.1(s), neither the Company, its directors or officers, or any Affiliates or agents of the Company, have withdrawn or paid cash to any vendor in an aggregate amount that exceeds Five Thousand Dollars (\$5,000) for any purpose.

(t) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(u) Certain Fees. Other than as set forth on Schedule 3.1(u), no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiaries to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchaser shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(v) Private Placement. Assuming the accuracy of each Purchaser's representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.



(w) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an “investment company” within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an “investment company” subject to registration under the Investment Company Act of 1940, as amended.

(x) Registration Rights. Other than as set forth on Schedule 3.1(x) and pursuant to this Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiaries.

(y) Listing and Maintenance Requirements; Trading Market Regulation. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC reports, the Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(z) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company’s amended and restated certificate of incorporation, as amended (or similar charter documents), or the laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company’s issuance of the Securities and the Purchaser’s ownership of the Securities.

(aa) Disclosure. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(bb) No Integrated Offering. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(cc) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchaser and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds; (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law; or (iv) violated in any material respect any provision of FCPA.

(ee) Accountants. The Company's accounting firm is set forth on Schedule 3.1(ee). To the knowledge and belief of the Company, such accounting firm is a registered public accounting firm as required by the Exchange Act.

(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

(gg) Acknowledgment Regarding Purchaser's Purchase of Securities. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by the Purchaser or any of their respective representatives or agents in connection

with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Securities. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Securities.

(ii) Stock Option Plans. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their respective financial results or prospects.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Promotional Stock Activities. Neither the Company, its officers, its directors, nor any affiliates or agents of the Company have engaged in any stock promotional activity that could give rise to a complaint, inquiry, or trading suspension by the Commission alleging (i) a violation of the anti-fraud provisions of the federal securities laws, (ii) violations of the anti-touting provisions, (iii) improper "gun-jumping"; or (iv) promotion without proper disclosure of compensation.

(nn) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(oo) Seniority. As of the Closing Date, other than as set forth on Schedule 3.1(oo), no Indebtedness or other claim against the Company is senior to the Notes in right of payment, whether with respect to interest or upon liquidation or dissolution, or otherwise, other than indebtedness secured by purchase money security interests (which is senior only as to underlying assets covered thereby) and capital lease obligations (which is senior only as to the property covered thereby).

(pp) No “Off-balance Sheet Arrangements”. Other than as set forth in Schedule 3.1(pp), neither the Company nor any of its Affiliates is involved in any “Off-balance Sheet Arrangements”. For purposes hereof an “Off-balance Sheet Arrangement” means any transaction or contract to which an entity unconsolidated with the Company or any of its Affiliates is a party and under which either the Company or any such Affiliate has: (i) any obligation under a guarantee contract pursuant to which the Company or any of its Affiliates could be required to make payments to the guaranteed party, including any standby letter of credit, market value guarantee, performance guarantee, indemnification agreement, keep-well or other support agreement; (ii) any retained or contingent interest in assets transferred to such unconsolidated entity that serves as credit, liquidity or market risk support to the entity in respect of such assets; (iii) any variable interest held in such unconsolidated entity where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with the Company of any of its Affiliates; and (iv) any liability or obligation of the same nature as those described in clauses (i) through (iii) of this sentence even if of a different name (whether absolute, accrued, contingent or otherwise) that would not be required to be reflected in the Company or any of its Affiliates’ financial statements.

(qq) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the “Money Laundering Laws”), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(rr) Subsidiary Rights. The Company has the unrestricted right to vote, and (subject to limitations imposed by applicable law) to receive dividends and distributions on, all capital securities of each of its Subsidiaries as owned by the Company or any Subsidiary.

(ss) Shell Company Status. The Company has never been, and is not presently, an issuer identified as a Shell Company.

(tt) Investor Relations. Other than as set forth in Schedule 3.1(tt), the Company is not currently a party, nor does it intend to become a party, to any agreement pursuant to which the Company will receive investor relations services.

(uu) Full Disclosure. No representation or warranty by the Company in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to the Purchasers pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

(vv) No Bad Actor Disqualification Event. After reasonable inquiry, none of the “Bad Actor” disqualifying events described in Rule 506(d)(1) under the Securities Act (a “Disqualification Event”) is applicable to Company or to Company’s knowledge any of its Affiliates, except a Disqualification Event as to which Rule 506(d)(2)(iii) applies.

(ww) Company has not, and will not, engage in any directed selling efforts in the United States in respect of the Securities. Company is offering and selling the Securities only to non U.S. Persons, in compliance with the offering restriction requirements of Regulation S.

3.2 Representations and Warranties of the Purchaser. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by the Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance

with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. The Purchaser understands that the Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account (this representation and warranty not limiting the Purchaser's right to sell the Securities in compliance with applicable federal and state securities laws). The Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Securities, it was, and as of the date hereof it is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. The Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of the Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of the Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(g) Non U.S. Person. The Purchaser is not a “U.S. Person” as that term is defined in Regulation S under the Securities Act, and is not acquiring the Securities for the account or beneficial ownership of any U.S. Person.

(h) No Short Sales. Neither Purchaser nor any Affiliate of Purchaser (i) holds any short position in the Common Stock, (ii) has ever engaged in, directly or indirectly, any Short Sale of the Common Stock, or (iii) has ever engaged in, directly or indirectly, any hedging transaction with regard to the Common Stock.

(i) Not a Bad Actor. After reasonable inquiry, none of the “Bad Actor” disqualifying events described in Rule 506(d)(1) under the Securities Act is applicable to the Purchaser or any of its Affiliates. The Purchaser is not now, and has never been, subject to any final cease and desist order or any penalty from the Commission or any court of competent jurisdiction for any violation of any provision of the Securities Act or the Exchange Act, or any of the regulations promulgated thereunder.

(j) Not an Affiliate. The Purchaser is not now, and has never been, an Affiliate of the Company or any other Purchaser. The Purchaser is not now, and has never been, part of any group of Persons that would be required under Section 13(d) of the Exchange Act, or the rules and regulations promulgated thereunder, to file a statement on Schedule 13D or Schedule 13G with regard to the Company.

The Company acknowledges and agrees that the representations contained in Section 3.2 shall not modify, amend or affect the Purchaser’s right to rely on the Company’s representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

#### **ARTICLE IV. OTHER AGREEMENTS OF THE PARTIES**

##### **4.1 Transfer Restrictions.**

(a) The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, at the Company’s sole expense in the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchaser agrees to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON REGULATION S OR AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO REGULATION S OR AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

The Company acknowledges and agrees that the Purchaser may from time to time pledge, pursuant to a bona fide margin agreement with a registered broker-dealer, or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement, the Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the Company's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities.

4.2 [Reserved].

4.3 [Reserved].

4.4 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.5 [Reserved].



4.6 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an “acquiring person” or such similar term under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchaser.

4.7 [Reserved].

4.8 Use of Proceeds. The Company shall use the net proceeds as set forth in Schedule 4.8.

4.9 Indemnification of Purchaser. Subject to the provisions of this Section 4.9, the Company will indemnify and hold the Purchaser and its directors, officers, managers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, managers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a “Purchaser Party”) harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys’ fees and costs of investigation that any the Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based in whole or in part upon a breach of the Purchaser Party’s representations, warranties or covenants under the Transaction Documents or any agreements or understandings the Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by the Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of the Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (x) for any settlement by a Purchaser Party effected without the Company’s prior

written consent, which shall not be unreasonably withheld or delayed; or (y) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnification contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 [Reserved].

4.11 Certain Transactions. The Purchaser covenants and agrees that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any Short Sales of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Company's Common Stock) during the period commencing with the execution of this Agreement and ending on the earlier of the Maturity Date (as defined in the Notes) of the Notes or the full repayment of the Notes; provided that this provision shall not operate to restrict a Purchaser's trading under any prior securities purchase agreement containing contractual rights that explicitly protects such trading in respect of the previously issued securities.

4.12 Securities Laws Disclosure; Publicity. The Company and the Purchaser shall consult with each other in issuing any public disclosure with respect to the transactions contemplated hereby, and neither the Company nor the Purchaser shall issue any such public disclosure nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or rules of the principal Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of the Purchaser, or include the name of the Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of the Purchaser, except: (a) as required by federal securities law in connection with any registration statement contemplated by this Agreement and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchaser with prior notice of such disclosure permitted under this clause (b).

4.13 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchaser at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

(a) For so long as any of the Notes remain outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price.

(b) For as long as any of the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will (without the prior written consent of the Purchaser), directly or indirectly: (a) solicit, initiate, encourage or accept any other inquiries, proposals or offers from any Person relating to any exchange (i) of any security of the Company or any of its Subsidiaries for any other security of the Company or any of its Subsidiaries, except to the extent (x) consummated pursuant to the terms of Common Share Equivalents of the Company as in effect as of the date hereof and disclosed in filings with the Commission prior to the date hereof (without giving effect to any amendment, modification, change or waiver of any terms thereof occurring on or after the date hereof or not disclosed in a filing by the Company with the Commission prior to the date hereof) or (ii) of any indebtedness or other securities of, or claim against, the Company or any of its Subsidiaries pursuant to a registration statement filed with the Commission or relying on any exemption under the Securities Act (including, without limitation, Section 3(a)(10) of the Securities Act (any such transaction described in clauses (i) or (ii), an “Exchange Transaction”); (b) enter into, effect, alter, amend, announce or recommend to its stockholders any Exchange Transaction with any Person; or (c) participate in any discussions, conversations, negotiations or other communications with any Person regarding any Exchange Transaction, or furnish to any Person any information with respect to any Exchange Transaction, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to seek an Exchange Transaction involving the Company or any of its Subsidiaries. For as long as the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will, directly or indirectly, cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to effect any acquisition of securities or indebtedness of, or claim against, the Company by such Person from an existing holder of such securities, indebtedness or claim in connection with a proposed exchange of such securities or

indebtedness of, or claim against, the Company (whether pursuant to Section 3(a)(9) or 3(a)(10) of the Securities Act or otherwise) (a “Third Party Exchange Transfer”). The Company, its affiliates and Subsidiaries, and each of its and their respective officers, employees, directors, agents or other representatives shall immediately cease and cause to be terminated all existing discussions, conversations, negotiations and other communications with any Persons with respect to any of the foregoing. For all purposes of this Agreement, violations of the restrictions set forth in this Section 4.14 by any Subsidiary or affiliate of the Company, or any officer, employee, director, agent or other representative of the Company or any of its Subsidiaries or affiliates shall be deemed a direct breach of this Section 4.14 by the Company.

(c) From the date hereof until sixty (60) calendar days after the Closing Date, neither the Company nor any Subsidiary shall, directly or indirectly, except with respect to the proposed \$20,000,000 private investment in public equities contemplated to be completed by May 31, 2019, and as otherwise permitted under this Agreement, issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any “equity security” (as that term is defined under Rule 405 promulgated under the Securities Act), any Common Shares or Common Share Equivalents, any debt securities, any preferred stock or any purchase rights) or otherwise amend, modify, waiver or alter any terms of conditions of any Common Share Equivalents outstanding as of the date hereof to decrease the exercise, conversion and/or exchange price, as applicable, thereunder or otherwise increase the aggregate number of Common Shares issuable in connection therewith.

(d) The Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding the foregoing, this Section 4.14 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.15. Regulation S Compliance. Each Purchaser agrees that, during the six (6) months following the Closing, it shall not engage in any transaction involving any securities of the Company that would be prohibited or restricted by, or would otherwise render unavailable any applicable safe harbor provided by Regulation S.

## **ARTICLE V. MISCELLANEOUS**

5.1 Termination. This Agreement may be terminated by the Purchaser, as to the Purchaser’s obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before April 28, 2019; provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. The Company has agreed to bear all fees, disbursements, and expenses in connection with the transactions contemplated herein, including, without limitation, the Company's legal and accounting fees and disbursements, the costs incident to the preparation, printing and distribution of any registration statement, filing fees, UCC fees, and costs associated with the Intellectual Property Security Agreement. The Company shall pay all stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers in connection with the transactions contemplated hereby.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties hereto acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries to be provided by the Purchaser hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, New York 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Purchaser delivered in accordance with this Section 5.4. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service addressed to each Purchaser at the email address, facsimile number, or address of the Purchaser appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Purchaser. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers holding at least 50.1% in interest of the Notes, including the holders of the Rosalind Notes, then outstanding or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any

such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 No Assignment. No party may assign this Agreement or any rights or obligations hereunder.

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Sections 4.9 and 5.5.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever the Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then the Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to the Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Usury. To the extent it may lawful do so, the Company hereby agrees not to insist upon or plead or in any manner whatsoever claim, and will resist any and all efforts to be compelled to take the benefit or advantage of, usury laws wherever enacted, now or at any time hereafter in force, in connection with any claim, action or proceeding that may be brought by the Purchaser in order to enforce any right or remedy under any Transaction Document. Notwithstanding any provision to the contrary contained in any Transaction Document, it is expressly agreed and provided that the total liability of the Company under the Transaction Documents for payments in the nature of interest shall not exceed the maximum lawful rate authorized under applicable law (the "Maximum Rate"), and, without limiting the foregoing, in no event shall any rate of interest or default interest, or both of them, when aggregated with any other sums in the nature of interest that the Company may be obligated to pay under the Transaction Documents exceed such Maximum Rate. It is agreed that if the maximum contract rate of interest allowed by law and applicable to the Transaction Documents is increased or decreased by statute or any official governmental action subsequent to the date hereof, the new maximum contract rate of interest allowed by law will be the Maximum Rate applicable to the Transaction Documents from the effective date thereof forward, unless such application is precluded by applicable law. If under any circumstances whatsoever, interest in excess of the Maximum Rate is paid by the Company to the Purchaser with respect to indebtedness evidenced by the Transaction Documents, such excess shall be applied by the Purchaser to the unpaid principal balance of any such indebtedness or be refunded to the Company, the manner of handling such excess to be at the Purchaser's election.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been cancelled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.



5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL**. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

*[Signature Pages Follow]*

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**DELCATH SYSTEMS, INC.**

Address for Notice:

By: \_\_\_\_\_  
Name:  
Title:

1633 Broadway  
Suite 22C  
New York, New York 10019  
Attention: Barbra Keck  
E-Mail: [bkeck@delcath.com](mailto:bkeck@delcath.com)

With a copy to (which shall not constitute notice):

Wexler Burkhardt Hirschberg & Unger, LLP

377 Oak Street  
Concourse Level  
Garden City, NY 11530  
Attention: Jolie Kahn  
e-mail: [jkahn@WBHULAW.COM](mailto:jkahn@WBHULAW.COM)

**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]**

**[PURCHASER SIGNATURE PAGES TO DELCATH SYSTEMS, INC. SECURITIES PURCHASE AGREEMENT]**

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: Rosalind Opportunities Fund I LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.)  
of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:  
Title of Authorized Signatory:  
Email Address of Authorized Signatory:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount:           \$ \_\_\_\_\_

Name of Purchaser: Rosalind Master Fund LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.)  
of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:  
Title of Authorized Signatory:  
Email Address of Authorized Signatory:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount:           \$ \_\_\_\_\_

**SCHEDULE OF PURCHASERS**

<b>(1) Purchaser</b>	<b>(2) Principal Amount of Notes</b>	<b>(3) Subscription Amount</b>
Rosalind Opportunities Fund I LP	\$550,000	\$550,000
Rosalind Master Fund LP	\$370,000	\$370,000

**EXHIBIT A**

**Form of Senior Secured Promissory Notes**

**EXHIBIT B**

**Form of Intellectual Property Security Agreement**

**EXHIBIT C**

**Form of Security Agreement**

**EXHIBIT D**

**Form of Subsidiary Guarantee**



**DISCLOSURE SCHEDULES TO THE**

**SECURITIES PURCHASE AGREEMENT**

**BY AND AMONG DELCATH SYSTEMS, INC. AND EACH OF THE PURCHASERS SIGNATORY THERETO**

**DATED April 26, 2019**

These Sections (these “**Sections**”) of this Disclosure Schedule are numbered to correspond to the corresponding sections of the Securities Purchase Agreement (the “**Agreement**”). These Sections have been prepared in accordance with, and subject to, the following terms and conditions:

(a) To the extent a Section is intended to qualify a representation or warranty of the Company contained in the Article III of the Agreement, the information and disclosures contained in such Section are intended only to qualify and limit such representation or warranty and not in any way expand the scope or effect of such representation or warranty.

(b) The disclosure of any item in any Section of this Disclosure Schedule will constitute disclosure for purposes of another Section if it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other Sections or Sub-Sections.

(c) Inclusion of any item in a Section of this Disclosure Schedule does not constitute a determination by the Company that such item is material and shall not be deemed to establish a standard or materiality. No disclosure in any Section of this Disclosure Schedule relating to any possible breach or violation of any agreement, law or any potential adverse contingency shall be construed as an admission or indication that any such breach or violation exists or has actually occurred or that such adverse contingency will actually occur.

(d) Any capitalized terms not defined in this Disclosure Schedule shall have the meanings assigned thereto in the Agreement. Any section headings or titles used herein are included for convenience only and shall not be considered as representations or warranties as to the type, character or content of the matters referred to thereunder.

**SCHEDULE 3.1(a)**

## **SUBSIDIARIES OF THE COMPANY**

1. Delcath Holdings Limited
2. Delcath Systems Limited
3. Delcath Systems UK Limited
4. Delcath Systems GmbH
5. Delcath Systems B.V.

**Organization and Qualification**

The Company is not in good standing in the State of Delaware as a result of its inability to pay the franchise taxes due in March 2019.

The Company is not in good standing in the State of New York as a result of its inability to pay taxes due in March 2019.

**Conflicts**

None.

**Capitalization**

- A. Shares beneficially owned by Affiliates: 1,284,329
- B. 12.6 million shares issued since most recent periodic report

Rights of Participation:  
 September 2017 Hudson Bay and Alto  
 February 2018: Registered Direct Investors  
 to the Securities Purchase Agreement dated as of June 4, 2018.

Delcath Systems, Inc.  
 Capitalization Table as of April 22, 2019

	<u>Authorized</u>	<u>Issued</u>	<u>Treasury</u>	<u>Outstanding</u>	
Preferred Shares	10,000,000	-	-	-	
Common Shares	1,000,000,000	18,277,807	-	18,277,807	
Fully diluted common shares:					
Feb 2015 Warrants (\$0.01; exp 2/2020)				9	
July 2015 Warrants (\$0.01; exp 7/2020)				9	
Oct 2016 Warrants (\$0.01; exp 10/2021)				11	
Feb 2018 Warrants (\$10.00; exp 2/2024)				189,000	
June 2018 Warrants (\$0.01, exp through 6/2024)				16,615,317	
June 2018 Warrants (\$4.00; exp 6/2023)				1,116,256	
July 2018 Warrants (\$0.01, exp through 7/2024)				12,168,926	
July 2018 Warrants (\$4.00 exp 7/2023)				785,737	
August 2018 Warrants (\$0.01, exp through 8/2024)				23,777,381	
August 2018 Warrants (\$1.75; exp 8/2023)				2,021,410	
Sept 2018 Warrants (\$0.01, exp through 9/2024)				830,854	
Sept 2018 Warrants (\$1.75; exp 9/2023)				279,506	
Options				<u>1,250,000</u>	
<b>Total shares reserved for warrants and options</b>					59,034,416
<b>Total shares issued and reserved:</b>					<u><u>77,312,223</u></u>

**Corporate Governance of Delcath Systems, Inc.**

Roger Stoll, Ph.D., Chairman

William Rueckert

Dr. Marco Taglietti

Dr. Jennifer Simpson

Audit Committee – William Rueckert, Chair; Roger Stoll

Compensation Committee – Marco Taglietti, Chair; William Rueckert

Nominating and Corp. Governance Committee – Roger Stoll, Chair; William Rueckert; Marco Taglietti

**Indebtedness**

1. Letter of credit issued by Silicon Valley Bank to Kasowitz, Benson, Torres and Friedman LLP with face amount of \$130,663.00.
2. Letter of credit issued by Silicon Valley Bank to SLG 810 7th Avenue Lessee LLC with face amount of \$881,297.08.
3. Indebtedness in a maximum amount of \$75,000 owed to Silicon Valley Bank under corporate credit card services agreement.
4. Indebtedness between Delcath Systems, Inc. and Delcath Holdings Limited pursuant to a License and Agreement to Share Intangible Development Costs dated as of January 1, 2012.
5. Indebtedness of \$5,478,559 between Delcath Systems, Inc. and Rosalind Master Fund L.P., as assigned to Rosalind Master Fund L.P. by Discover Growth Fund and Discover Growth Fund, LLC as signatories to Securities Purchase Agreements dated as of June 4, 2018; July 20, 2018; August 29, 2018; and a Note Purchase and Exchange Agreement dated March 29, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
6. Indebtedness of \$469,975 between Delcath Systems, Inc. and the institutional investors signatory to Securities Purchase Agreements dated as of September 21, 2018 and the 8% Senior Secured Convertible Promissory Notes issued pursuant thereto.
7. Indebtedness of \$180,000 between Delcath Systems, Inc. and Rosalind Master Fund L.P. as signatory to the Securities Purchase Agreement dated as of April 18, 2019 and the 8% Senior Secured Promissory Note issued pursuant thereto.

**Existing Liens**

1. Liens of Silicon Valley Bank on account nos. 3301246486 and 3301264690, respectively, securing the letters of credit described in numbers 1 and 2 above.
2. Lien of Silicon Valley Bank account no. 3301464115 securing the Indebtedness described in number 3 above.
3. Lien of the institutional investor securing the Obligations described in numbers 5 -7 above.

**SEC Reports; Financial Statements**

The Company has not timely filed its Annual Report on Form 10-K for the year ended December 31, 2018.



**Material Changes; Undisclosed Events, Liabilities or Developments**

See Schedule 3.1(m).

**Litigation**

1. In March 2019, the Company sued two affiliated Iroquois Funds and FirstFire seeking declaratory judgment, among other remedies, that the February 2018 warrants issued to them are deemed to not including an “exploding” antidilution feature upon a down round financing. The suit was filed in New York State Supreme Court in NY County, NY.

See Schedule 3.1(m) below for any potential claims.

**Compliance**

UBC Demand Letter for \$2,106,116.00.

Payables to Roth Capital in the amount of \$552,642.60.

Notices of Default from Discover Growth Fund, Discover Growth Fund, LLC, Bigger Capital Fund, LP and District 2 Capital Fund LP in respect of the Indebtedness listed in paragraph 5 of Schedule 3.1(h).

**Title to Assets**

See Schedule 3.1(h).

**Material Agreements**

See Schedule 3.1(m).

**Intellectual Property**

None.

**Transactions with Affiliates and Employees**

Herein below are all back salaries and unreimbursed employee expenses through April 15, 2019:

Jennifer Simpson	\$ 862,376
Barbra Keck	\$ 536,181
John Purpura	\$ 553,491
All other employees	\$ 335,670
	\$ 2,287,718

**Cash Payments**

None.



**Certain Fees**

Fees to Roth Capital Partners, LLC under waiver letter with Roth Capital Partners, LLC  
Fees to Think Equity under Engagement Letter

**Registration Rights**

Warrants issued in February 2018

September 21, 2018 Securities Purchase Agreement

**Accountants**

Marcum LLP

Grant Thornton LLP (with respect to 2015, 2016 and 2017 audited financials only)

**Seniority**

See Schedule 3.1(h).

**Off-balance Sheet Arrangements**

None.

**Investor Relations**

Use of Proceeds

General working capital purposes.

## SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of May 9, 2019, by and among Delcath Systems, Inc., a Delaware corporation (the "Company"), and the purchasers identified on the signature pages hereto (each, a "Purchaser," or in the aggregate, the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), Regulation S and Rule 506(b) promulgated thereunder, the Company desires to sell, and the Purchasers desire to purchase from the Company, the Securities (as defined herein).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

**ARTICLE I.  
DEFINITIONS**

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement: (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Transaction Documents (as defined herein), and (b) the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"BHCA" shall have the meaning ascribed to such term in Section 3.1(l).

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

"Closing Date" means the Trading Day(s) on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto in connection with a Closing, and all conditions precedent to (i) the Purchaser's obligations to pay the Subscription Amount as to the Closing and (ii) the Company's obligations to deliver the Securities as to the Closing, in each case, have been satisfied or waived.

"Closing" means closing of the purchase and sale of the Securities pursuant to Section 2.2.



“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Disclosure Schedules” shall have the meaning ascribed to such term in Section 3.1.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(t).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exchange Transaction” shall have the meaning ascribed to such term in Section 4.15(b).

“Exempt Issuance” means the issuance of (a) shares of Common Stock, restricted stock units or options to employees, officers, directors, advisors or independent contractors of the Company pursuant to any stock or option plan duly adopted for such purpose, (b) shares of Common Stock, warrants or options to advisors or independent contractors of the Company for compensatory purposes, (c) securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date hereof, provided that such securities have not been amended since the date hereof to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, (d) securities issuable pursuant to any contractual anti-dilution, most favored nations or similar obligations of the Company in effect as of the date hereof, provided that such obligations have not been materially amended since the date of hereof, and (e) securities issued pursuant to acquisitions or any other strategic transactions approved by the Board of Directors, provided that any such issuance shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“Federal Reserve” shall have the meaning ascribed to such term in Section 3.1(l).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Guarantors” mean collectively, the Subsidiaries of the Company who are party to the Subsidiary Guarantee.

“Indebtedness” means except for Permitted Indebtedness, (a) any liabilities for borrowed money or amounts owed in excess of \$100,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$100,000 due under leases required to be capitalized in accordance with GAAP.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(q).

“Intellectual Property Security Agreement” means that certain Intellectual Property Security Agreement required to be delivered pursuant to Section 2.3 of this Agreement, in the form attached hereto as Exhibit B.

“Liabilities” means all direct or indirect liabilities, Indebtedness and obligations of any kind of Company to the Purchaser, howsoever created, arising or evidenced, whether now existing or hereafter arising (including those acquired by assignment), absolute or contingent, due or to become due, primary or secondary, joint or several, whether existing or arising through discount, overdraft, purchase, direct loan, participation, operation of law, or otherwise, including, but not limited to, pursuant to the Note, this Agreement and/or any of the other Transaction Documents, all accrued but unpaid interest on the Note, any letter of credit, any standby letter of credit, and/or outside attorneys’ and paralegals’ fees or charges relating to the preparation of the Transaction Documents and the enforcement of the Purchaser’s rights, remedies and powers under this Agreement, the Note and/or the other Transaction Documents.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Maximum Rate” shall have the meaning ascribed to such term in Section 5.17.

“Money Laundering Laws” shall have the meaning ascribed to such term in Section 3.1(qq).

“Notes” means collectively, the 8% Senior Secured Promissory Notes issued by the Company to each Purchaser hereunder, each in the form of Exhibit A attached hereto.

“Off-balance Sheet Arrangement” shall have the meaning ascribed to such term in Section 3.1(pp).

“Permitted Indebtedness” means the letters of credit and secured accounts listed in Schedule 3.1(h).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Principal Amount” means, as to the Purchaser, the principal amount of the Notes set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto in United States Dollars.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.9.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rosalind Notes” means the Notes originally held by Rosalind Opportunities Fund I LP and Rosalind Master Fund LP.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities” means the Notes to be issued to the Purchaser pursuant to this Agreement.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Security Agreement” means the Security Agreement dated on the date hereof by and among the Company, the Company’s Subsidiaries, and the Purchaser, as hereinafter amended and/or supplemented altogether with all exhibits, schedules and annexes to such Security Agreement, pursuant to which all Liabilities of the Company to the Purchaser under the Transaction Documents are secured by the Collateral (as defined in the Security Agreement), which security interest in the Collateral shall be perfected by the Purchaser’s UCC-1, filed with the Secretary of State of the State of Delaware, to the extent perfectable by the filing of a UCC-1 Financing Statement, or if applicable, a UCC-3 Financing Statement Amendment and such other documents and instruments related thereto, which Security Agreement is annexed hereto as Exhibit C.

“Shell Company” means an entity that fits within the definition of “shell company” under Section 12b-2 of the Exchange Act and Rule 144.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act.

“Subscription Amount” means, as to the Purchaser, the aggregate amount to be paid for the Notes purchased hereunder as specified below the Purchaser’s name on the signature page of this Agreement and next to the heading “Subscription Amount,” in United States dollars and in immediately available funds.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Subsidiary Guarantee” means the Subsidiary Guarantee, dated as of the date hereof, pursuant to which the Subsidiaries have jointly and severally agreed to guarantee and act as surety for the Company’s obligation to repay the Notes, in the form attached hereto as Exhibit D.

“Third Party Exchange Transfer” shall have the meaning ascribed to such term in Section 4.14(b).

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; OTC Markets or the OTC Bulletin Board (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Notes, the Security Agreement, the Intellectual Property Security Agreement, the Subsidiary Guarantee and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.14(a).

## **ARTICLE II. PURCHASE AND SALE**

2.1 Purchase. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company shall sell and issue to each Purchaser, and each Purchaser shall purchase, severally and not jointly, from the Company, Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto. The purchase of the Notes will be completed in a single tranche as provided herein.

2.2 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and each Purchaser agrees to purchase, the Subscription Amount of Notes as set forth on the signature page hereto executed by such Purchaser. At the Closing, each Purchaser shall deliver to the Company, via wire transfer to an account designated by the Company, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to such Purchaser its Notes as set forth in Section 2.3(a), and the Company and such Purchaser shall deliver the other items set forth in Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4 for Closing, such Closing shall be undertaken remotely by electronic exchange of Closing documentation. There may be multiple closings so long as at each Closing the obligations under Section 2.3 are met.

2.3 Deliveries.

(a) On or prior to the Closing Date (except as otherwise agreed by the Purchaser), the Company shall deliver or cause to be delivered to each Purchaser the following:

- (i) this Agreement duly executed by the Company;
- (ii) the Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser's name in column (2) on the Schedule of Purchasers attached hereto, registered in the name of the Purchaser;
- (iii) the Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Security Agreement);
- (iv) the Intellectual Property Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Intellectual Property Security Agreement);
- (v) the Subsidiary Guarantee, duly executed by the Company's Subsidiaries (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Subsidiary Guarantee);
- (vi) a certificate evidencing the Company's qualification as a foreign corporation and good standing issued by the Secretary of State (or comparable office) of each jurisdiction, if any, in which the Company conducts business and is required to so qualify, as of a date within ten (10) days of the Closing Date; and
- (vii) such other documents, instruments or certificates relating to the transactions contemplated by this Agreement as such Purchaser or its counsel may reasonably request.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, as applicable, the following:

- (i) this Agreement, duly executed by the Purchaser;
- (ii) the Purchaser's Subscription Amount by wire transfer to the account specified in writing by the Company;
- (iii) the Security Agreement, duly executed by the Purchaser; and
- (iv) the Intellectual Property Security Agreement, duly executed by the Purchaser.

2.4 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

- (i) the accuracy in all material respects as at Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);
- (ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed; and
- (iii) the delivery by the Purchaser of the items set forth in Section 2.3(b) of this Agreement.

(b) The respective obligations of each Purchaser hereunder in connection with the Closing are subject to the following conditions being met:

- (i) the accuracy in all material respects when made as to the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);
- (ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;
- (iii) the delivery by the Company of the items set forth in Section 2.3(a) of this Agreement;
- (iv) there is no existing Event of Default (as defined in the Notes) and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default;

- (v) there is no breach of any obligations, covenants and agreements under the Transaction Documents and no existing event which, with the passage of time or the giving of notice, would constitute a breach under the Transaction Documents;
- (vi) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;
- (vii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of the Purchaser, and without regard to any factors unique to the Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing;
- (viii) [reserved];
- (ix) [reserved]; and
- (x) any other conditions contained herein or the other Transaction Documents, including, without limitation those set forth in Section 2.3 herein.

2.5 Minimum and Maximum. Each Purchaser must purchase Securities for a minimum subscription amount of at least \$100,000. Provided, however, that if necessary to meet Company's existing obligations under rights of participation, the minimum subscription amount per party may be reduced pro rata to the extent necessary to enable all persons with such rights that desire to participate to so participate. The aggregate subscription amount for all securities to all Purchasers may not exceed \$4,000,000.

### **ARTICLE III. REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the disclosure schedules attached hereto (the "Disclosure Schedules"), which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company (which for purposes of this Section 3.1 means the Company and all of its Subsidiaries) hereby makes the following representations and warranties to each Purchaser as of the Closing Date:

(a) Subsidiaries. All of the direct and indirect Subsidiaries and parent entities of the Company are set forth on Schedule 3.1(a) hereto. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, other than as set forth on Schedule 3.1(a) hereto, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized and validly existing, and, other than as set forth on Schedule 3.1(b) hereto, the Company is in good standing, under the laws of the jurisdiction of its incorporation or organization, as applicable, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary or parent entity of the Company is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document; (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, its parent entities and the Subsidiaries, taken as a whole; or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.



(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not, except as set forth on Schedule 3.1(d): (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents; (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien (except Liens in favor of the Purchaser) upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected; or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.13 of this Agreement; (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Securities in the time and manner required thereby; and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization; Corporate Governance.

(i) The capitalization of the Company is as set forth on Schedule 3.1(g)(i), which Schedule 3.1(g)(i) shall also include (A) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof and (B) the number of authorized and reserved shares of capital stock of the Company. The Company has not issued capital stock since its most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i), except the issuance of shares of Common Stock to employees

pursuant to the Company's employee stock purchase plans and except pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents except as set forth on Schedule 3.1(g)(i). There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents except as set forth on Schedule 3.1(g)(i). The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities except as set forth on Schedule 3.1(g)(i). All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders' agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(ii) The names and titles of each of the Company's principal officers, directors and beneficial holders of at least five percent (5%) of the outstanding shares of each class of the Company's capital stock on a fully diluted basis are as set forth on Schedule 3.1(g)(ii), which Schedule 3.1(g)(ii) shall also include each committee of directors as well as the names and titles of each director currently serving on each such committee.

(h) Indebtedness. Schedule 3.1(h) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Except as set forth on Schedule 3.1(h), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(i) SEC Reports; Financial Statements. Other than as set forth on Schedule 3.1(i) hereto, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”). As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the Company’s Annual Report on Form 10-K, including such latest audited financial statements, or in a subsequent SEC Report filed prior to the date hereof and except as set forth in Schedule 3.1(g), Schedule 3.1(m), and Schedule 3.1(j): (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect; (ii) the Company has not incurred any liabilities or obligations (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in filings made with the Commission; (iii) the Company has not altered its method of accounting; (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock; (v) the Company has not sold, assigned or transferred any other tangible assets or Intellectual Property Rights, or canceled any debts or claims, except in the ordinary course of business, (vi) the Company has not suffered any substantial loss contingencies or waived any rights of material value, whether or not in the ordinary course of business, or suffered the loss of any material amount of prospective business, (vii) the Company has not entered into any acquisition or financing transactions, whether or not in the ordinary course of business, other than with respect to the Transaction Documents and (v) the Company has not issued any equity securities to any officer, director or Affiliate,

no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties except as set forth in Schedule 3.1(k), or against or affecting the Company's current or former officers or directors in their capacity as such, before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company that is likely to lead to action that can reasonably be expected to result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary, except as set forth in Schedule 3.1(m): (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived); (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority; or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (“Material Permits”), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except as set forth in Schedule 3.1(o) and except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Material Agreements. Except for the Transaction Documents (with respect to clause (i) only) or as set forth on Schedule 3.1(p) hereto, or as would not be reasonably likely to have a Material Adverse Effect, (i) the Company and each of its Subsidiaries have performed all obligations required to be performed by them to date under any written or oral contract, instrument, agreement, commitment, obligation, plan or arrangement, filed or required to be filed with the Commission (the “Material Agreements”), (ii) neither the Company nor any of its Subsidiaries has received any notice of default under any Material Agreement and, (iii) to the best of the Company's knowledge, neither the Company nor any of its Subsidiaries is in default under any Material Agreement now in effect.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as presently conducted and which the failure to so have could have a Material Adverse Effect (collectively, the “Intellectual Property Rights”). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights except as disclosed in Schedule 3.1(q). The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) Transactions with Affiliates and Employees. Except as disclosed in Schedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from providing for the borrowing of money from or lending of money to, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for: (i) payment of salary or consulting fees for services rendered; (ii) reimbursement for expenses incurred on behalf of the Company; and (iii) other employee benefits.

(s) Payments of Cash. Except as disclosed on Schedule 3.1(s), neither the Company, its directors or officers, or any Affiliates or agents of the Company, have withdrawn or paid cash to any vendor in an aggregate amount that exceeds Five Thousand Dollars (\$5,000) for any purpose.

(t) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(u) Certain Fees. Other than as set forth on Schedule 3.1(u), no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiaries to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchaser shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(v) Private Placement. Assuming the accuracy of each Purchaser's representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

(w) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an “investment company” within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an “investment company” subject to registration under the Investment Company Act of 1940, as amended.

(x) Registration Rights. Other than as set forth on Schedule 3.1(x) and pursuant to this Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiaries.

(y) Listing and Maintenance Requirements; Trading Market Regulation. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC reports, the Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(z) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company’s amended and restated certificate of incorporation, as amended (or similar charter documents), or the laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company’s issuance of the Securities and the Purchaser’s ownership of the Securities.

(aa) Disclosure. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.



(bb) No Integrated Offering. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(cc) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchaser and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds; (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law; or (iv) violated in any material respect any provision of FCPA.

(ee) Accountants. The Company's accounting firm is set forth on Schedule 3.1(ee). To the knowledge and belief of the Company, such accounting firm is a registered public accounting firm as required by the Exchange Act.

(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

(gg) Acknowledgment Regarding Purchaser's Purchase of Securities. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by the Purchaser or any of their respective representatives or agents in

connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Securities. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Securities.

(ii) Stock Option Plans. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their respective financial results or prospects.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Promotional Stock Activities. Neither the Company, its officers, its directors, nor any affiliates or agents of the Company have engaged in any stock promotional activity that could give rise to a complaint, inquiry, or trading suspension by the Commission alleging (i) a violation of the anti-fraud provisions of the federal securities laws, (ii) violations of the anti-touting provisions, (iii) improper “gun-jumping”; or (iv) promotion without proper disclosure of compensation.

(nn) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(oo) Seniority. As of the Closing Date, other than as set forth on Schedule 3.1(oo), no Indebtedness or other claim against the Company is senior to the Notes in right of payment, whether with respect to interest or upon liquidation or dissolution, or otherwise, other than indebtedness secured by purchase money security interests (which is senior only as to underlying assets covered thereby) and capital lease obligations (which is senior only as to the property covered thereby).

(pp) No “Off-balance Sheet Arrangements”. Other than as set forth in Schedule 3.1(pp), neither the Company nor any of its Affiliates is involved in any “Off-balance Sheet Arrangements”. For purposes hereof an “Off-balance Sheet Arrangement” means any transaction or contract to which an entity unconsolidated with the Company or any of its Affiliates is a party and under which either the Company or any such Affiliate has: (i) any obligation under a guarantee contract pursuant to which the Company or any of its Affiliates could be required to make payments to the guaranteed party, including any standby letter of credit, market value guarantee, performance guarantee, indemnification agreement, keep-well or other support agreement; (ii) any retained or contingent interest in assets transferred to such unconsolidated entity that serves as credit, liquidity or market risk support to the entity in respect of such assets; (iii) any variable interest held in such unconsolidated entity where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with the Company of any of its Affiliates; and (iv) any liability or obligation of the same nature as those described in clauses (i) through (iii) of this sentence even if of a different name (whether absolute, accrued, contingent or otherwise) that would not be required to be reflected in the Company or any of its Affiliates’ financial statements.

(qq) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the “Money Laundering Laws”), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(rr) Subsidiary Rights. The Company has the unrestricted right to vote, and (subject to limitations imposed by applicable law) to receive dividends and distributions on, all capital securities of each of its Subsidiaries as owned by the Company or any Subsidiary.

(ss) Shell Company Status. The Company has never been, and is not presently, an issuer identified as a Shell Company.

(tt) Investor Relations. Other than as set forth in Schedule 3.1(tt), the Company is not currently a party, nor does it intend to become a party, to any agreement pursuant to which the Company will receive investor relations services.

(uu) Full Disclosure. No representation or warranty by the Company in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to the Purchasers pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

(vv) No Bad Actor Disqualification Event. After reasonable inquiry, none of the “Bad Actor” disqualifying events described in Rule 506(d)(1) under the Securities Act (a “Disqualification Event”) is applicable to Company or to Company’s knowledge any of its Affiliates, except a Disqualification Event as to which Rule 506(d)(2)(iii) applies.

(ww) Company has not, and will not, engage in any directed selling efforts in the United States in respect of the Securities. Company is offering and selling the Securities only to non U.S. Persons, in compliance with the offering restriction requirements of Regulation S.

3.2 Representations and Warranties of the Purchaser. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by the Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. The Purchaser understands that the Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account (this representation and warranty not limiting the Purchaser's right to sell the Securities in compliance with applicable federal and state securities laws). The Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Securities, it was, and as of the date hereof it is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. The Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of the Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of the Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(g) Non U.S. Person. The Purchaser is not a "U.S. Person" as that term is defined in Regulation S under the Securities Act, and is not acquiring the Securities for the account or beneficial ownership of any U.S. Person.

(h) No Short Sales. Neither Purchaser nor any Affiliate of Purchaser (i) holds any short position in the Common Stock, (ii) has ever engaged in, directly or indirectly, any Short Sale of the Common Stock, or (iii) has ever engaged in, directly or indirectly, any hedging transaction with regard to the Common Stock.

(i) Not a Bad Actor. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d)(1) under the Securities Act is applicable to the Purchaser or any of its Affiliates. The Purchaser is not now, and has never been, subject to any final cease and desist order or any penalty from the Commission or any court of competent jurisdiction for any violation of any provision of the Securities Act or the Exchange Act, or any of the regulations promulgated thereunder.

(j) Not an Affiliate. The Purchaser is not now, and has never been, an Affiliate of the Company or any other Purchaser. The Purchaser is not now, and has never been, part of any group of Persons that would be required under Section 13(d) of the Exchange Act, or the rules and regulations promulgated thereunder, to file a statement on Schedule 13D or Schedule 13G with regard to the Company.

The Company acknowledges and agrees that the representations contained in Section 3.2 shall not modify, amend or affect the Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

**ARTICLE IV.  
OTHER AGREEMENTS OF THE PARTIES**

4.1 Transfer Restrictions.

(a) The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, at the Company's sole expense in the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchaser agrees to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON REGULATION S OR AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO REGULATION S OR AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

The Company acknowledges and agrees that the Purchaser may from time to time pledge, pursuant to a bona fide margin agreement with a registered broker-dealer, or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement, the Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the Company's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities.

4.2 [Reserved].

4.3 [Reserved].

4.4 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.5 [Reserved].

4.6 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an “acquiring person” or such similar term under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchaser.

4.7 [Reserved].

4.8 Use of Proceeds. The Company shall use the net proceeds as set forth in Schedule 4.8.

4.9 Indemnification of Purchaser. Subject to the provisions of this Section 4.9, the Company will indemnify and hold the Purchaser and its directors, officers, managers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, managers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a “Purchaser Party”) harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys’ fees and costs of investigation that any the Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based in whole or in part upon a breach of the Purchaser Party’s representations, warranties or covenants



under the Transaction Documents or any agreements or understandings the Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by the Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of the Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (x) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (y) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnification contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 [Reserved].

4.11 Certain Transactions. The Purchaser covenants and agrees that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any Short Sales of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Company's Common Stock) during the period commencing with the execution of this Agreement and ending on the earlier of the Maturity Date (as defined in the Notes) of the Notes or the full repayment of the Notes; provided that this provision shall not operate to restrict a Purchaser's trading under any prior securities purchase agreement containing contractual rights that explicitly protects such trading in respect of the previously issued securities.

4.12 Securities Laws Disclosure; Publicity. The Company and the Purchaser shall consult with each other in issuing any public disclosure with respect to the transactions contemplated hereby, and neither the Company nor the Purchaser shall issue any such public disclosure nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or rules of the principal Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of the Purchaser, or include the name of the Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of the Purchaser, except: (a) as required by federal securities law in connection with any registration statement contemplated by this Agreement and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchaser with prior notice of such disclosure permitted under this clause (b).

4.13 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchaser at the Closing under applicable securities or “Blue Sky” laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

4.14 Subsequent Equity Sales.

(a) For so long as any of the Notes remain outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price.

(b) For as long as any of the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will (without the prior written consent of the Purchaser), directly or indirectly: (a) solicit, initiate, encourage or accept any other inquiries, proposals or offers from any Person relating to any exchange (i) of any security of the Company or any of its Subsidiaries for any other security of the Company or any of its Subsidiaries, except to the extent (x) consummated pursuant to the terms of Common Share Equivalents of the Company as in effect as of the date hereof and disclosed in filings with the Commission prior to the date hereof (without giving effect to any amendment, modification, change or waiver of any terms thereof occurring on or after the date hereof or not disclosed in a filing by the Company with the Commission prior to the date hereof) or (ii) of any indebtedness or other securities of, or claim against, the Company or any of its Subsidiaries pursuant to a registration statement filed with the Commission or relying on any exemption under the Securities Act (including, without limitation, Section 3(a)(10) of the Securities Act (any such transaction described in clauses (i) or (ii), an “Exchange Transaction”); (b) enter into, effect, alter, amend, announce or recommend to its stockholders any Exchange Transaction with any Person; or (c) participate in any discussions, conversations, negotiations or other communications with any Person regarding any Exchange Transaction, or furnish to any Person any information with respect to any Exchange Transaction, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to seek an Exchange Transaction involving the Company or any of its Subsidiaries. For as long as the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will, directly or indirectly, cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to effect any acquisition of securities or indebtedness of, or claim against, the Company by such Person from an existing holder of such securities, indebtedness or claim in connection with a proposed exchange of such securities or indebtedness of, or claim against, the Company (whether pursuant to Section 3(a)(9) or 3(a)(10) of the Securities Act or otherwise) (a “Third Party Exchange Transfer”). The Company, its affiliates and Subsidiaries, and each of its and their respective officers, employees, directors, agents or other representatives shall immediately cease and cause to be terminated all existing discussions, conversations, negotiations and other communications with any Persons with respect to any of the foregoing. For all purposes of this Agreement, violations of the restrictions set forth in this Section 4.14 by any Subsidiary or affiliate of the Company, or any officer, employee, director, agent or other representative of the Company or any of its Subsidiaries or affiliates shall be deemed a direct breach of this Section 4.14 by the Company.

(c) From the date hereof until sixty (60) calendar days after the Closing Date, neither the Company nor any Subsidiary shall, directly or indirectly, except with respect to the proposed \$20,000,000 private investment in public equities contemplated to be completed by May 31, 2019, and as otherwise permitted under this Agreement, issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any “equity

security” (as that term is defined under Rule 405 promulgated under the Securities Act), any Common Shares or Common Share Equivalents, any debt securities, any preferred stock or any purchase rights) or otherwise amend, modify, waiver or alter any terms of conditions of any Common Share Equivalents outstanding as of the date hereof to decrease the exercise, conversion and/or exchange price, as applicable, thereunder or otherwise increase the aggregate number of Common Shares issuable in connection therewith.

(d) The Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding the foregoing, this Section 4.14 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.15. Regulation S Compliance. Each Purchaser agrees that, during the six (6) months following the Closing, it shall not engage in any transaction involving any securities of the Company that would be prohibited or restricted by, or would otherwise render unavailable any applicable safe harbor provided by Regulation S.

4.16. Opinion. The Company shall, forthwith (and in any event within 5 days) upon request of any Purchaser, deliver to the Purchasers an opinion of the Company’s counsel with respect to the Company, the Transaction Documents and the security granted in connection therewith, in form and substance satisfactory to the Purchasers.

## **ARTICLE V. MISCELLANEOUS**

5.1 Termination. This Agreement may be terminated by the Purchaser, as to the Purchaser’s obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before May 10, 2019; provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. The Company has agreed to bear all fees, disbursements, and expenses in connection with the transactions contemplated herein, including, without limitation, the Company’s legal and accounting fees and disbursements, the costs incident to the preparation, printing and distribution of any registration statement, filing fees, UCC fees, and costs associated with the Intellectual Property Security Agreement. The Company shall pay all stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers in connection with the transactions contemplated hereby.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties hereto acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries to be provided by the Purchaser hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, New York 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Purchaser delivered in accordance with this Section 5.4. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service addressed to each Purchaser at the email address, facsimile number, or address of the Purchaser appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Purchaser. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers holding at least 50.1% in interest of the Notes, including the holders of the Rosalind Notes, then outstanding or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 No Assignment. No party may assign this Agreement or any rights or obligations hereunder.

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Sections 4.9 and 5.5.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever the Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then the Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to the Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Usury. To the extent it may lawful do so, the Company hereby agrees not to insist upon or plead or in any manner whatsoever claim, and will resist any and all efforts to be compelled to take the benefit or advantage of, usury laws wherever enacted, now or at any time hereafter in force, in connection with any claim, action or proceeding that may be brought by the Purchaser in order to enforce any right or remedy under any Transaction Document. Notwithstanding any provision to the contrary contained in any Transaction Document, it is expressly agreed and provided that the total liability of the Company under the Transaction Documents for payments in the nature of interest shall not exceed the maximum lawful rate authorized under applicable law (the “Maximum Rate”), and, without limiting the foregoing, in no event shall any rate of interest or default interest, or both of them, when aggregated with any other sums in the nature of interest that the Company may be obligated to pay under the Transaction Documents exceed such Maximum Rate. It is agreed that if the maximum contract rate of interest allowed by law and applicable to the Transaction Documents is increased or decreased by statute or any official governmental action subsequent to the date hereof, the new maximum contract rate of interest allowed by law will be the Maximum Rate applicable to the Transaction Documents from the effective date thereof forward, unless such application is precluded by applicable law. If under any circumstances whatsoever, interest in excess of the Maximum Rate is paid by the Company to the Purchaser with respect to indebtedness evidenced by the Transaction Documents, such excess shall be applied by the Purchaser to the unpaid principal balance of any such indebtedness or be refunded to the Company, the manner of handling such excess to be at the Purchaser’s election.

5.18 Liquidated Damages. The Company’s obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been cancelled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

*[Signature Pages Follow]*



IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**DELCATH SYSTEMS, INC.**

Address for Notice:

By: \_\_\_\_\_  
Name:  
Title:

1633 Broadway  
Suite 22C  
New York, New York 10019  
Attention: Barbra Keck  
E-Mail: [bkeck@delcath.com](mailto:bkeck@delcath.com)

With a copy to (which shall not constitute notice):

Wexler Burkhart Hirschberg & Unger, LLP

377 Oak Street  
Concourse Level  
Garden City, NY 11530  
Attention: Jolie Kahn  
e-mail: [jkahn@WBHULAW.COM](mailto:jkahn@WBHULAW.COM)

**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]**

**[PURCHASER SIGNATURE PAGES TO DELCATH SYSTEMS, INC. SECURITIES PURCHASE AGREEMENT]**

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: Rosalind Opportunities Fund I LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:

\_\_\_\_\_

Title of Authorized Signatory:

\_\_\_\_\_

Email Address of Authorized Signatory:

\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount:      \$550,000

Name of Purchaser: Rosalind Master Fund LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:

\_\_\_\_\_

Title of Authorized Signatory:

\_\_\_\_\_

Email Address of Authorized Signatory:

\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount:      \$550,000

**SCHEDULE OF PURCHASERS**

<b>(1)</b> <b>Purchaser</b>	<b>(2)</b> <b>Principal Amount of</b> <b>Notes</b>	<b>(3)</b> <b>Subscription Amount</b>
--------------------------------	----------------------------------------------------------	------------------------------------------

Rosalind Opportunities Fund I LP

\$550,000

\$550,000

Rosalind Master Fund LP

\$550,000

\$550,000

**EXHIBIT A**

**Form of Senior Secured Promissory Notes**

**EXHIBIT B**

**Form of Intellectual Property Security Agreement**

**EXHIBIT C**

**Form of Security Agreement**

**EXHIBIT D**

**Form of Subsidiary Guarantee**

**DISCLOSURE SCHEDULES TO THE**

**SECURITIES PURCHASE AGREEMENT**

**BY AND AMONG DELCATH SYSTEMS, INC. AND EACH OF THE PURCHASERS SIGNATORY THERETO**

**DATED May 9, 2019**

These Sections (these “**Sections**”) of this Disclosure Schedule are numbered to correspond to the corresponding sections of the Securities Purchase Agreement (the “**Agreement**”). These Sections have been prepared in accordance with, and subject to, the following terms and conditions:

(a) To the extent a Section is intended to qualify a representation or warranty of the Company contained in the Article III of the Agreement, the information and disclosures contained in such Section are intended only to qualify and limit such representation or warranty and not in any way expand the scope or effect of such representation or warranty.

(b) The disclosure of any item in any Section of this Disclosure Schedule will constitute disclosure for purposes of another Section if it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other Sections or Sub-Sections.

(c) Inclusion of any item in a Section of this Disclosure Schedule does not constitute a determination by the Company that such item is material and shall not be deemed to establish a standard or materiality. No disclosure in any Section of this Disclosure Schedule relating to any possible breach or violation of any agreement, law or any potential adverse contingency shall be construed as an admission or indication that any such breach or violation exists or has actually occurred or that such adverse contingency will actually occur.

(d) Any capitalized terms not defined in this Disclosure Schedule shall have the meanings assigned thereto in the Agreement. Any section headings or titles used herein are included for convenience only and shall not be considered as representations or warranties as to the type, character or content of the matters referred to thereunder.



**SUBSIDIARIES OF THE COMPANY**

1. Delcath Holdings Limited
2. Delcath Systems Limited
3. Delcath Systems UK Limited
4. Delcath Systems GmbH
5. Delcath Systems B.V.

**Organization and Qualification**

None.

**Conflicts**

None.

**Capitalization**

- A. Shares beneficially owned by Affiliates: 1,284,329
- B. 12.6 million shares issued since most recent periodic report

**Rights of Participation:**

September 2017 Hudson Bay and Alto

February 2018: Registered Direct Investors

June 2018: Discover Growth Fund, as assigned to Rosalind Master Fund LP by Discover Growth Fund as signatory to the Securities Purchase Agreement dated as of June 4, 2018.

Delcath Systems, Inc.  
Capitalization Table as of April 22, 2019

	<u>Authorized</u>	<u>Issued</u>	<u>Treasury</u>	<u>Outstanding</u>	
Preferred Shares	10,000,000	-	-	-	
Common Shares	1,000,000,000	18,277,807	-	18,277,807	
Fully diluted common shares:					
Feb 2015 Warrants (\$0.01; exp 2/2020)				9	
July 2015 Warrants (\$0.01; exp 7/2020)				9	
Oct 2016 Warrants (\$0.01; exp 10/2021)				11	
Feb 2018 Warrants (\$10.00; exp 2/2024)				189,000	
June 2018 Warrants (\$0.01; exp through 6/2024)				16,615,317	
June 2018 Warrants (\$4.00; exp 6/2023)				1,116,256	
July 2018 Warrants (\$0.01, exp through 7/2024)				12,168,926	
July 2018 Warrants (\$4.00 exp 7/2023)				785,737	
August 2018 Warrants (\$0.01 exp through 8/2024)				23,777,381	
August 2018 Warrants (\$1.75; exp 8/2023)				2,021,410	
Sept 2018 Warrants (\$0.01, exp through 9/2024)				830,854	
Sept 2018 Warrants (\$1.75; exp 9/2023)				279,506	
Options				<u>1,250,000</u>	
<b>Total shares reserved for warrants and options</b>					59,034,416
<b>Total shares issued and reserved:</b>					<u><u>77,312,223</u></u>

**Corporate Governance of Delcath Systems, Inc.**

Roger Stoll, Ph.D., Chairman

William Rueckert

Dr. Marco Taglietti

Dr. Jennifer Simpson

Audit Committee – William Rueckert, Chair; Roger Stoll

Compensation Committee – Marco Taglietti, Chair; William Rueckert

Nominating and Corp. Governance Committee – Roger Stoll, Chair; William Rueckert; Marco Taglietti

**Indebtedness**

1. Letter of credit issued by Silicon Valley Bank to Kasowitz, Benson, Torres and Friedman LLP with face amount of \$130,663.00.
2. Letter of credit issued by Silicon Valley Bank to SLG 810 7th Avenue Lessee LLC with face amount of \$881,297.08.
3. Indebtedness in a maximum amount of \$75,000 owed to Silicon Valley Bank under corporate credit card services agreement.
4. Indebtedness between Delcath Systems, Inc. and Delcath Holdings Limited pursuant to a License and Agreement to Share Intangible Development Costs dated as of January 1, 2012.
5. Indebtedness of \$5,478,559 between Delcath Systems, Inc. and Rosalind Master Fund L.P., as assigned to Rosalind Master Fund LP by Discover Growth Fund and Discover Growth Fund, LLC as signatories to Securities Purchase Agreements dated as of June 4, 2018; July 20, 2018; August 29, 2018; and a Note Purchase and Exchange Agreement dated March 29, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
6. Indebtedness of \$469,975 between Delcath Systems, Inc. and the institutional investors signatory to Securities Purchase Agreements dated as of September 21, 2018 and the 8% Senior Secured Convertible Promissory Notes issued pursuant thereto.
7. Indebtedness of \$180,000 between Delcath Systems, Inc. and Rosalind Master Fund LP as signatory to the Securities Purchase Agreement dated as of April 18, 2019 and the 8% Senior Secured Promissory Note issued pursuant thereto.
8. Indebtedness of \$370,000 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$550,000 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of April 26, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.

**Existing Liens**

1. Liens of Silicon Valley Bank on account nos. 3301246486 and 3301264690, respectively, securing the letters of credit described in numbers 1 and 2 above.
2. Lien of Silicon Valley Bank account no. 3301464115 securing the Indebtedness described in number 3 above.
3. Lien of the institutional investor securing the Obligations described in numbers 5 -8 above.

**SEC Reports; Financial Statements**

The Company has not timely filed its Annual Report on Form 10-K or its Proxy Statement for the year ended December 31, 2018.

The Company will not timely file its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

**Material Changes; Undisclosed Events, Liabilities or Developments**

See Schedule 3.1(m).



**Litigation**

1. In March 2019, the Company sued two affiliated Iroquois Funds and FirstFire seeking declaratory judgment, among other remedies, that the February 2018 warrants issued to them are deemed to not including an “exploding” antidilution feature upon a down round financing. The suit was filed in New York State Supreme Court in NY County, NY.

See Schedule 3.1(m) below for any potential claims.

**Compliance**

UBC Demand Letter for \$2,106,116.00.

Payables to Roth Capital in the amount of \$552,642.60.

Notices of Default from Discover Growth Fund, Discover Growth Fund, LLC, Bigger Capital Fund, LP and District 2 Capital Fund LP in respect of the Indebtedness listed in paragraph 5 of Schedule 3.1(h).

**Title to Assets**

See Schedule 3.1(h).

**Material Agreements**

See Schedule 3.1(m).

**Intellectual Property**

None.

**Transactions with Affiliates and Employees**

Herein below are all back salaries and unreimbursed employee expenses through April 15, 2019:

Jennifer Simpson	\$ 862,376
Barbra Keck	\$ 536,181
John Purpura	\$ 553,491
All other employees	\$ 335,670
	\$ 2,287,718

Cash Payments

None.

**Certain Fees**

Fees to Roth Capital Partners, LLC under waiver letter with Roth Capital Partners, LLC  
Fees to Think Equity under Engagement Letter



**Registration Rights**

Warrants issued in February 2018

September 21, 2018 Securities Purchase Agreement

Accountants

Marcum LLP

Grant Thornton LLP (with respect to 2015, 2016 and 2017 audited financials only)

Seniority

See Schedule 3.1(h).

**Off-balance Sheet Arrangements**

None.

**Investor Relations**

None.

**Use of Proceeds**

General working capital purposes.

**SECURITIES PURCHASE AGREEMENT**

This Securities Purchase Agreement (this "Agreement") is dated as of May 23, 2019, by and among Delcath Systems, Inc., a Delaware corporation (the "Company"), and the purchasers identified on the signature pages hereto (each, a "Purchaser," or in the aggregate, the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), Regulation S and Rule 506(b) promulgated thereunder, the Company desires to sell, and the Purchasers desire to purchase from the Company, the Securities (as defined herein).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

**ARTICLE I.  
DEFINITIONS**

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement: (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Transaction Documents (as defined herein), and (b) the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"BHCA" shall have the meaning ascribed to such term in Section 3.1(l).

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

"Closing Date" means the Trading Day(s) on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto in connection with a Closing, and all conditions precedent to (i) the Purchaser's obligations to pay the Subscription Amount as to the Closing and (ii) the Company's obligations to deliver the Securities as to the Closing, in each case, have been satisfied or waived.

"Closing" means closing of the purchase and sale of the Securities pursuant to Section 2.2.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Disclosure Schedules” shall have the meaning ascribed to such term in Section 3.1.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(t).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exchange Transaction” shall have the meaning ascribed to such term in Section 4.15(b).

“Exempt Issuance” means the issuance of (a) shares of Common Stock, restricted stock units or options to employees, officers, directors, advisors or independent contractors of the Company pursuant to any stock or option plan duly adopted for such purpose, (b) shares of Common Stock, warrants or options to advisors or independent contractors of the Company for compensatory purposes, (c) securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date hereof, provided that such securities have not been amended since the date hereof to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, (d) securities issuable pursuant to any contractual anti-dilution, most favored nations or similar obligations of the Company in effect as of the date hereof, provided that such obligations have not been materially amended since the date of hereof, and (e) securities issued pursuant to acquisitions or any other strategic transactions approved by the Board of Directors, provided that any such issuance shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“Federal Reserve” shall have the meaning ascribed to such term in Section 3.1(ll).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Guarantors” mean collectively, the Subsidiaries of the Company who are party to the Subsidiary Guarantee.

“Indebtedness” means except for Permitted Indebtedness, (a) any liabilities for borrowed money or amounts owed in excess of \$100,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$100,000 due under leases required to be capitalized in accordance with GAAP.



“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(q).

“Intellectual Property Security Agreement” means that certain Intellectual Property Security Agreement required to be delivered pursuant to Section 2.3 of this Agreement, in the form attached hereto as Exhibit B.

“Liabilities” means all direct or indirect liabilities, Indebtedness and obligations of any kind of Company to the Purchaser, howsoever created, arising or evidenced, whether now existing or hereafter arising (including those acquired by assignment), absolute or contingent, due or to become due, primary or secondary, joint or several, whether existing or arising through discount, overdraft, purchase, direct loan, participation, operation of law, or otherwise, including, but not limited to, pursuant to the Note, this Agreement and/or any of the other Transaction Documents, all accrued but unpaid interest on the Note, any letter of credit, any standby letter of credit, and/or outside attorneys’ and paralegals’ fees or charges relating to the preparation of the Transaction Documents and the enforcement of the Purchaser’s rights, remedies and powers under this Agreement, the Note and/or the other Transaction Documents.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Maximum Rate” shall have the meaning ascribed to such term in Section 5.17.

“Money Laundering Laws” shall have the meaning ascribed to such term in Section 3.1(qq).

“Notes” means collectively, the 8% Senior Secured Promissory Notes issued by the Company to each Purchaser hereunder, each in the form of Exhibit A attached hereto.

“Off-balance Sheet Arrangement” shall have the meaning ascribed to such term in Section 3.1(pp).

“Permitted Indebtedness” means the letters of credit and secured accounts listed in Schedule 3.1(h).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Principal Amount” means, as to the Purchaser, the principal amount of the Notes set forth opposite such Purchaser’s name in column (2) on the Schedule of Purchasers attached hereto in United States Dollars.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.9.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rosalind Notes” means the Notes originally held by Rosalind Opportunities Fund I LP and Rosalind Master Fund LP.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities” means the Notes to be issued to the Purchaser pursuant to this Agreement.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Security Agreement” means the Security Agreement dated on the date hereof by and among the Company, the Company’s Subsidiaries, and the Purchaser, as hereinafter amended and/or supplemented altogether with all exhibits, schedules and annexes to such Security Agreement, pursuant to which all Liabilities of the Company to the Purchaser under the Transaction Documents are secured by the Collateral (as defined in the Security Agreement), which security interest in the Collateral shall be perfected by the Purchaser’s UCC-1, filed with the Secretary of State of the State of Delaware, to the extent perfectable by the filing of a UCC-1 Financing Statement, or if applicable, a UCC-3 Financing Statement Amendment and such other documents and instruments related thereto, which Security Agreement is annexed hereto as Exhibit C.

“Shell Company” means an entity that fits within the definition of “shell company” under Section 12b-2 of the Exchange Act and Rule 144.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act.

“Subscription Amount” means, as to the Purchaser, the aggregate amount to be paid for the Notes purchased hereunder as specified below the Purchaser’s name on the signature page of this Agreement and next to the heading “Subscription Amount,” in United States dollars and in immediately available funds.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Subsidiary Guarantee” means the Subsidiary Guarantee, dated as of the date hereof, pursuant to which the Subsidiaries have jointly and severally agreed to guarantee and act as surety for the Company’s obligation to repay the Notes, in the form attached hereto as Exhibit D.

“Third Party Exchange Transfer” shall have the meaning ascribed to such term in Section 4.14(b).

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; OTC Markets or the OTC Bulletin Board (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Notes, the Security Agreement, the Intellectual Property Security Agreement, the Subsidiary Guarantee and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.14(a).

**ARTICLE II.**  
**PURCHASE AND SALE**

2.1 Purchase. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company shall sell and issue to each Purchaser, and each Purchaser shall purchase, severally and not jointly, from the Company, Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser's name in column (2) on the Schedule of Purchasers attached hereto. The purchase of the Notes will be completed in a single tranche as provided herein.

2.2 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and each Purchaser agrees to purchase, the Subscription Amount of Notes as set forth on the signature page hereto executed by such Purchaser. At the Closing, each Purchaser shall deliver to the Company, via wire transfer to an account designated by the Company, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to such Purchaser its Notes as set forth in Section 2.3(a), and the Company and such Purchaser shall deliver the other items set forth in Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4 for Closing, such Closing shall be undertaken remotely by electronic exchange of Closing documentation. There may be multiple closings so long as at each Closing the obligations under Section 2.3 are met.

2.3 Deliveries.

(a) On or prior to the Closing Date (except as otherwise agreed by the Purchaser), the Company shall deliver or cause to be delivered to each Purchaser the following:

- (i) this Agreement duly executed by the Company;
- (ii) the Notes with an aggregate Principal Amount equal to the amount set forth opposite such Purchaser's name in column (2) on the Schedule of Purchasers attached hereto, registered in the name of the Purchaser;
- (iii) the Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Security Agreement);
- (iv) the Intellectual Property Security Agreement, duly executed by the Company (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Intellectual Property Security Agreement);

(v) the Subsidiary Guarantee, duly executed by the Company's Subsidiaries (and for all Closings after the first Closing, additional Purchasers shall merely sign a signature page and be an additional party to the Subsidiary Guarantee);

(vi) a certificate evidencing the Company's qualification as a foreign corporation and good standing issued by the Secretary of State (or comparable office) of each jurisdiction, if any, in which the Company conducts business and is required to so qualify, as of a date within ten (10) days of the Closing Date; and

(vii) such other documents, instruments or certificates relating to the transactions contemplated by this Agreement as such Purchaser or its counsel may reasonably request.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, as applicable, the following:

(i) this Agreement, duly executed by the Purchaser;

(ii) the Purchaser's Subscription Amount by wire transfer to the account specified in writing by the Company;

(iii) the Security Agreement, duly executed by the Purchaser; and

(iv) the Intellectual Property Security Agreement, duly executed by the Purchaser.

#### 2.4 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects as at Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by the Purchaser of the items set forth in Section 2.3(b) of this Agreement.

- (b) The respective obligations of each Purchaser hereunder in connection with the Closing are subject to the following conditions being met:
- (i) the accuracy in all material respects when made as to the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);
  - (ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;
  - (iii) the delivery by the Company of the items set forth in Section 2.3(a) of this Agreement;
  - (iv) there is no existing Event of Default (as defined in the Notes) and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default;
  - (v) there is no breach of any obligations, covenants and agreements under the Transaction Documents and no existing event which, with the passage of time or the giving of notice, would constitute a breach under the Transaction Documents;
  - (vi) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;
  - (vii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of the Purchaser, and without regard to any factors unique to the Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing;
  - (viii) [reserved];
  - (ix) [reserved]; and
  - (x) any other conditions contained herein or the other Transaction Documents, including, without limitation those set forth in Section 2.3 herein.

2.5 Minimum and Maximum. Each Purchaser must purchase Securities for a minimum subscription amount of at least \$100,000. Provided, however, that if necessary to meet Company's existing obligations under rights of participation, the minimum subscription amount per party may be reduced pro rata to the extent necessary to enable all persons with such rights that desire to participate to so participate. The aggregate subscription amount for all securities to all Purchasers may not exceed \$4,000,000.

### **ARTICLE III. REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the disclosure schedules attached hereto (the "Disclosure Schedules"), which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company (which for purposes of this Section 3.1 means the Company and all of its Subsidiaries) hereby makes the following representations and warranties to each Purchaser as of the Closing Date:

(a) Subsidiaries. All of the direct and indirect Subsidiaries and parent entities of the Company are set forth on Schedule 3.1(a) hereto. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, other than as set forth on Schedule 3.1(a) hereto, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized and validly existing, and, other than as set forth on Schedule 3.1(b) hereto, the Company is in good standing, under the laws of the jurisdiction of its incorporation or organization, as applicable, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary or parent entity of the Company is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document; (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, its parent entities and the Subsidiaries, taken as a whole; or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not, except as set forth on Schedule 3.1(d): (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents; (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien (except Liens in favor of the Purchaser) upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected; or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to



Section 4.13 of this Agreement; (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Securities in the time and manner required thereby; and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the “Required Approvals”).

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization; Corporate Governance.

(i) The capitalization of the Company is as set forth on Schedule 3.1(g)(i), which Schedule 3.1(g)(i) shall also include (A) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof and (B) the number of authorized and reserved shares of capital stock of the Company. The Company has not issued capital stock since its most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i), except the issuance of shares of Common Stock to employees pursuant to the Company’s employee stock purchase plans and except pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents except as set forth on Schedule 3.1(g)(i). There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents except as set forth on Schedule 3.1(g)(i). The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities except as set forth on Schedule 3.1(g)(i). All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders’ agreements, voting agreements or other similar agreements with respect to the Company’s capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company’s stockholders.

(ii) The names and titles of each of the Company's principal officers, directors and beneficial holders of at least five percent (5%) of the outstanding shares of each class of the Company's capital stock on a fully diluted basis are as set forth on Schedule 3.1(g)(ii), which Schedule 3.1(g)(ii) shall also include each committee of directors as well as the names and titles of each director currently serving on each such committee.

(h) Indebtedness. Schedule 3.1(h) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Except as set forth on Schedule 3.1(h), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(i) SEC Reports; Financial Statements. Other than as set forth on Schedule 3.1(i) hereto, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Reports"). As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the Company's Annual Report on Form 10-K, including such latest audited financial statements, or in a subsequent SEC Report filed prior to the date hereof and except as set forth in Schedule 3.1(g), Schedule 3.1(m), and Schedule 3.1(j): (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect; (ii) the Company has not incurred any liabilities or obligations (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial

statements pursuant to GAAP or disclosed in filings made with the Commission; (iii) the Company has not altered its method of accounting; (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock; (v) the Company has not sold, assigned or transferred any other tangible assets or Intellectual Property Rights, or canceled any debts or claims, except in the ordinary course of business, (vi) the Company has not suffered any substantial loss contingencies or waived any rights of material value, whether or not in the ordinary course of business, or suffered the loss of any material amount of prospective business, (vii) the Company has not entered into any acquisition or financing transactions, whether or not in the ordinary course of business, other than with respect to the Transaction Documents and (v) the Company has not issued any equity securities to any officer, director or Affiliate, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties except as set forth in Schedule 3.1(k), or against or affecting the Company's current or former officers or directors in their capacity as such, before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company that is likely to lead to action that can reasonably be expected to result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary, except as set forth in Schedule 3.1(m): (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived); (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority; or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except as set forth in Schedule 3.1(q) and except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Material Agreements. Except for the Transaction Documents (with respect to clause (i) only) or as set forth on Schedule 3.1(p) hereto, or as would not be reasonably likely to have a Material Adverse Effect, (i) the Company and each of its Subsidiaries have performed all obligations required to be performed by them to date under any written or oral contract, instrument, agreement, commitment, obligation, plan or arrangement, filed or required to be filed with the Commission (the "Material Agreements"), (ii) neither the Company nor any of its Subsidiaries has received any notice of default under any Material Agreement and, (iii) to the best of the Company's knowledge, neither the Company nor any of its Subsidiaries is in default under any Material Agreement now in effect.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as presently conducted and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights except as disclosed in Schedule 3.1(q). The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) Transactions with Affiliates and Employees. Except as disclosed in Schedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from providing for the borrowing of money from or lending of money to, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for: (i) payment of salary or consulting fees for services rendered; (ii) reimbursement for expenses incurred on behalf of the Company; and (iii) other employee benefits.

(s) Payments of Cash. Except as disclosed on Schedule 3.1(s), neither the Company, its directors or officers, or any Affiliates or agents of the Company, have withdrawn or paid cash to any vendor in an aggregate amount that exceeds Five Thousand Dollars (\$5,000) for any purpose.

(t) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(u) Certain Fees. Other than as set forth on Schedule 3.1(u), no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiaries to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchaser shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(v) Private Placement. Assuming the accuracy of each Purchaser's representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

(w) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(x) Registration Rights. Other than as set forth on Schedule 3.1(x) and pursuant to this Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiaries.

(y) Listing and Maintenance Requirements; Trading Market Regulation. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC reports, the Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(z) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's amended and restated certificate of incorporation, as amended (or similar charter documents), or the laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchaser's ownership of the Securities.

(aa) Disclosure. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(bb) No Integrated Offering. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(cc) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchaser and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds; (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law; or (iv) violated in any material respect any provision of FCPA.

(ee) Accountants. The Company's accounting firm is set forth on Schedule 3.1(ee). To the knowledge and belief of the Company, such accounting firm is a registered public accounting firm as required by the Exchange Act.



(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

(gg) Acknowledgment Regarding Purchaser's Purchase of Securities. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by the Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Securities. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Securities.

(ii) Stock Option Plans. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their respective financial results or prospects.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the “BHCA”) and to regulation by the Board of Governors of the Federal Reserve System (the “Federal Reserve”). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Promotional Stock Activities. Neither the Company, its officers, its directors, nor any affiliates or agents of the Company have engaged in any stock promotional activity that could give rise to a complaint, inquiry, or trading suspension by the Commission alleging (i) a violation of the anti-fraud provisions of the federal securities laws, (ii) violations of the anti-touting provisions, (iii) improper “gun-jumping”; or (iv) promotion without proper disclosure of compensation.

(nn) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(oo) Seniority. As of the Closing Date, other than as set forth on Schedule 3.1(oo), no Indebtedness or other claim against the Company is senior to the Notes in right of payment, whether with respect to interest or upon liquidation or dissolution, or otherwise, other than indebtedness secured by purchase money security interests (which is senior only as to underlying assets covered thereby) and capital lease obligations (which is senior only as to the property covered thereby).

(pp) No “Off-balance Sheet Arrangements”. Other than as set forth in Schedule 3.1(pp), neither the Company nor any of its Affiliates is involved in any “Off-balance Sheet Arrangements”. For purposes hereof an “Off-balance Sheet Arrangement” means any transaction or contract to which an entity unconsolidated with the Company or any of its Affiliates is a party and under which either the Company or any such Affiliate has: (i) any obligation under a guarantee contract pursuant to which the Company or any of its Affiliates could be required to make payments to the guaranteed party, including any standby letter of credit, market value guarantee, performance guarantee, indemnification agreement, keep-well or other support agreement; (ii) any retained or contingent interest

in assets transferred to such unconsolidated entity that serves as credit, liquidity or market risk support to the entity in respect of such assets; (iii) any variable interest held in such unconsolidated entity where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with the Company of any of its Affiliates; and (iv) any liability or obligation of the same nature as those described in clauses (i) through (iii) of this sentence even if of a different name (whether absolute, accrued, contingent or otherwise) that would not be required to be reflected in the Company or any of its Affiliates' financial statements.

(qq) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(rr) Subsidiary Rights. The Company has the unrestricted right to vote, and (subject to limitations imposed by applicable law) to receive dividends and distributions on, all capital securities of each of its Subsidiaries as owned by the Company or any Subsidiary.

(ss) Shell Company Status. The Company has never been, and is not presently, an issuer identified as a Shell Company.

(tt) Investor Relations. Other than as set forth in Schedule 3.1(tt), the Company is not currently a party, nor does it intend to become a party, to any agreement pursuant to which the Company will receive investor relations services.

(uu) Full Disclosure. No representation or warranty by the Company in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to the Purchasers pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

(vv) No Bad Actor Disqualification Event. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d)(1) under the Securities Act (a "Disqualification Event") is applicable to Company or to Company's knowledge any of its Affiliates, except a Disqualification Event as to which Rule 506(d)(2)(iii) applies.

(ww) Company has not, and will not, engage in any directed selling efforts in the United States in respect of the Securities. Company is offering and selling the Securities only to non U.S. Persons, in compliance with the offering restriction requirements of Regulation S.

3.2 Representations and Warranties of the Purchaser. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by the Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. The Purchaser understands that the Securities are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account (this representation and warranty not limiting the Purchaser's right to sell the Securities in compliance with applicable federal and state securities laws). The Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Securities, it was, and as of the date hereof it is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. The Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of the Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of the Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(g) Non U.S. Person. The Purchaser is not a "U.S. Person" as that term is defined in Regulation S under the Securities Act, and is not acquiring the Securities for the account or beneficial ownership of any U.S. Person.

(h) No Short Sales. Neither Purchaser nor any Affiliate of Purchaser (i) holds any short position in the Common Stock, (ii) has ever engaged in, directly or indirectly, any Short Sale of the Common Stock, or (iii) has ever engaged in, directly or indirectly, any hedging transaction with regard to the Common Stock.

(i) Not a Bad Actor. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d)(1) under the Securities Act is applicable to the Purchaser or any of its Affiliates. The Purchaser is not now, and has never been, subject to any final cease and desist order or any penalty from the Commission or any court of competent jurisdiction for any violation of any provision of the Securities Act or the Exchange Act, or any of the regulations promulgated thereunder.

(j) Not an Affiliate. The Purchaser is not now, and has never been, an Affiliate of the Company or any other Purchaser. The Purchaser is not now, and has never been, part of any group of Persons that would be required under Section 13(d) of the Exchange Act, or the rules and regulations promulgated thereunder, to file a statement on Schedule 13D or Schedule 13G with regard to the Company.

The Company acknowledges and agrees that the representations contained in Section 3.2 shall not modify, amend or affect the Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

**ARTICLE IV.  
OTHER AGREEMENTS OF THE PARTIES**

4.1 Transfer Restrictions.

(a) The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, at the Company's sole expense in the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchaser agrees to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON REGULATION S OR AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO REGULATION S OR AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

The Company acknowledges and agrees that the Purchaser may from time to time pledge, pursuant to a bona fide margin agreement with a registered broker-dealer, or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement, the Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the Company's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities.

4.2 [Reserved].

4.3 [Reserved].

4.4 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.5 [Reserved].

4.6 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an “acquiring person” or such similar term under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchaser.

4.7 [Reserved].

4.8 Use of Proceeds. The Company shall use the net proceeds as set forth in Schedule 4.8.

4.9 Indemnification of Purchaser. Subject to the provisions of this Section 4.9, the Company will indemnify and hold the Purchaser and its directors, officers, managers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, managers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a “Purchaser Party”) harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys’ fees and costs of investigation that any the Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based in whole or in part upon a breach of the Purchaser Party’s representations, warranties or covenants

under the Transaction Documents or any agreements or understandings the Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by the Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of the Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (x) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (y) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnification contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 [Reserved].

4.11 Certain Transactions. The Purchaser covenants and agrees that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any Short Sales of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Company's Common Stock) during the period commencing with the execution of this Agreement and ending on the earlier of the Maturity Date (as defined in the Notes) of the Notes or the full repayment of the Notes; provided that this provision shall not operate to restrict a Purchaser's trading under any prior securities purchase agreement containing contractual rights that explicitly protects such trading in respect of the previously issued securities.

4.12 Securities Laws Disclosure; Publicity. The Company and the Purchaser shall consult with each other in issuing any public disclosure with respect to the transactions contemplated hereby, and neither the Company nor the Purchaser shall issue any such public disclosure nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or rules of the principal Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of



such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of the Purchaser, or include the name of the Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of the Purchaser, except: (a) as required by federal securities law in connection with any registration statement contemplated by this Agreement and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchaser with prior notice of such disclosure permitted under this clause (b).

4.13 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchaser at the Closing under applicable securities or “Blue Sky” laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

4.14 Subsequent Equity Sales.

(a) For so long as any of the Notes remain outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price.

(b) For as long as any of the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will (without the prior written consent of the Purchaser), directly or indirectly: (a) solicit, initiate, encourage or accept any other inquiries, proposals or offers from any Person relating to any exchange (i) of any security of the Company or any of its Subsidiaries for any other security of the Company or any of its Subsidiaries, except to the extent (x) consummated pursuant to the terms of Common Share Equivalents of the Company as in effect as of the date hereof and disclosed in filings with the Commission prior to the date hereof (without giving effect to any amendment, modification, change or waiver of any terms thereof occurring on or after the date hereof or not disclosed in a filing by the Company with the Commission prior to the date hereof) or (ii) of any indebtedness or other securities of, or claim against,

the Company or any of its Subsidiaries pursuant to a registration statement filed with the Commission or relying on any exemption under the Securities Act (including, without limitation, Section 3(a)(10) of the Securities Act (any such transaction described in clauses (i) or (ii), an “Exchange Transaction”); (b) enter into, effect, alter, amend, announce or recommend to its stockholders any Exchange Transaction with any Person; or (c) participate in any discussions, conversations, negotiations or other communications with any Person regarding any Exchange Transaction, or furnish to any Person any information with respect to any Exchange Transaction, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to seek an Exchange Transaction involving the Company or any of its Subsidiaries. For as long as the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will, directly or indirectly, cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to effect any acquisition of securities or indebtedness of, or claim against, the Company by such Person from an existing holder of such securities, indebtedness or claim in connection with a proposed exchange of such securities or indebtedness of, or claim against, the Company (whether pursuant to Section 3(a)(9) or 3(a)(10) of the Securities Act or otherwise) (a “Third Party Exchange Transfer”). The Company, its affiliates and Subsidiaries, and each of its and their respective officers, employees, directors, agents or other representatives shall immediately cease and cause to be terminated all existing discussions, conversations, negotiations and other communications with any Persons with respect to any of the foregoing. For all purposes of this Agreement, violations of the restrictions set forth in this Section 4.14 by any Subsidiary or affiliate of the Company, or any officer, employee, director, agent or other representative of the Company or any of its Subsidiaries or affiliates shall be deemed a direct breach of this Section 4.14 by the Company.

(c) From the date hereof until sixty (60) calendar days after the Closing Date, neither the Company nor any Subsidiary shall, directly or indirectly, except with respect to the proposed minimum \$20,000,000 private investment in public equities contemplated to be completed by June 7, 2019, and as otherwise permitted under this Agreement, issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any “equity security” (as that term is defined under Rule 405 promulgated under the Securities Act), any Common Shares or Common Share Equivalents, any debt securities, any preferred stock or any purchase rights) or otherwise amend, modify, waiver or alter any terms of conditions of any Common Share Equivalents outstanding as of the date hereof to decrease the exercise, conversion and/or exchange price, as applicable, thereunder or otherwise increase the aggregate number of Common Shares issuable in connection therewith.

(d) The Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding the foregoing, this Section 4.14 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.15. Regulation S Compliance. Each Purchaser agrees that, during the six (6) months following the Closing, it shall not engage in any transaction involving any securities of the Company that would be prohibited or restricted by, or would otherwise render unavailable any applicable safe harbor provided by Regulation S.

4.16. Opinion. The Company shall, forthwith (and in any event within 5 days) upon request of any Purchaser, deliver to the Purchasers an opinion of the Company's counsel with respect to the Company, the Transaction Documents and the security granted in connection therewith, in form and substance satisfactory to the Purchasers.

## **ARTICLE V. MISCELLANEOUS**

5.1 Termination. This Agreement may be terminated by the Purchaser, as to the Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before May 24, 2019; provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. The Company has agreed to bear all fees, disbursements, and expenses in connection with the transactions contemplated herein, including, without limitation, the Company's legal and accounting fees and disbursements, the costs incident to the preparation, printing and distribution of any registration statement, filing fees, UCC fees, and costs associated with the Intellectual Property Security Agreement. The Company shall pay all stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers in connection with the transactions contemplated hereby.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties hereto acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries to be provided by the Purchaser hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, New York 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Purchaser delivered in accordance with this Section 5.4. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight

courier service addressed to each Purchaser at the email address, facsimile number, or address of the Purchaser appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Purchaser. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers holding at least 50.1% in interest of the Notes, including the holders of the Rosalind Notes, then outstanding or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 No Assignment. No party may assign this Agreement or any rights or obligations hereunder.

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Sections 4.9 and 5.5.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever the Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then the Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to the Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Usury. To the extent it may lawful do so, the Company hereby agrees not to insist upon or plead or in any manner whatsoever claim, and will resist any and all efforts to be compelled to take the benefit or advantage of, usury laws wherever enacted, now or at any time hereafter in force, in connection with any claim, action or proceeding that may be brought by the Purchaser in order to enforce any right or remedy under any Transaction Document. Notwithstanding any provision to the contrary contained in any Transaction Document, it is expressly agreed and provided that the total liability of the Company under the Transaction Documents for payments in the nature of interest shall not exceed the maximum lawful rate authorized under applicable law (the "Maximum Rate"), and, without limiting the foregoing, in no event shall any rate of

interest or default interest, or both of them, when aggregated with any other sums in the nature of interest that the Company may be obligated to pay under the Transaction Documents exceed such Maximum Rate. It is agreed that if the maximum contract rate of interest allowed by law and applicable to the Transaction Documents is increased or decreased by statute or any official governmental action subsequent to the date hereof, the new maximum contract rate of interest allowed by law will be the Maximum Rate applicable to the Transaction Documents from the effective date thereof forward, unless such application is precluded by applicable law. If under any circumstances whatsoever, interest in excess of the Maximum Rate is paid by the Company to the Purchaser with respect to indebtedness evidenced by the Transaction Documents, such excess shall be applied by the Purchaser to the unpaid principal balance of any such indebtedness or be refunded to the Company, the manner of handling such excess to be at the Purchaser's election.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been cancelled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL.** IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

*[Signature Pages Follow]*

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**DELCATH SYSTEMS, INC.**

Address for Notice:

By: \_\_\_\_\_  
Name:  
Title:

1633 Broadway  
Suite 22C  
New York, New York 10019  
Attention: Barbra Keck  
E-Mail: [bkeck@delcath.com](mailto:bkeck@delcath.com)

With a copy to (which shall not constitute notice):

McCarter & English, LLP

100 Mulberry Street,  
Four Gateway Center  
Newark, New Jersey 07102  
Attention: David Broderick  
e-mail: [dbroderick@mccarter.com](mailto:dbroderick@mccarter.com)

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SIGNATURE PAGE FOR PURCHASER FOLLOWS]**



**[PURCHASER SIGNATURE PAGES TO DELCATH SYSTEMS, INC. SECURITIES PURCHASE AGREEMENT]**

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: Rosalind Opportunities Fund I LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Email Address of Authorized Signatory: \_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount: \$559,500.00

Name of Purchaser: Rosalind Master Fund LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Email Address of Authorized Signatory: \_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount: \$559,500.00

**SCHEDULE OF PURCHASERS**

<b>(1)</b> <b>Purchaser</b>	<b>(2)</b> <b>Principal Amount of</b> <b>Notes</b>	<b>(3)</b> <b>Subscription Amount</b>
Rosalind Opportunities Fund I LP	\$559,500.00	\$559,500.00
Rosalind Master Fund LP	\$559,500.00	\$559,500.00

**EXHIBIT A**

**Form of Senior Secured Promissory Notes**

**EXHIBIT B**

**Form of Intellectual Property Security Agreement**

**EXHIBIT C**

**Form of Security Agreement**

**EXHIBIT D**

**Form of Subsidiary Guarantee**

**DISCLOSURE SCHEDULES TO THE**

**SECURITIES PURCHASE AGREEMENT**

**BY AND AMONG DELCATH SYSTEMS, INC. AND EACH OF THE PURCHASERS SIGNATORY THERETO**

**DATED May 23, 2019**

These Sections (these “**Sections**”) of this Disclosure Schedule are numbered to correspond to the corresponding sections of the Securities Purchase Agreement (the “**Agreement**”). These Sections have been prepared in accordance with, and subject to, the following terms and conditions:

(a) To the extent a Section is intended to qualify a representation or warranty of the Company contained in the Article III of the Agreement, the information and disclosures contained in such Section are intended only to qualify and limit such representation or warranty and not in any way expand the scope or effect of such representation or warranty.

(b) The disclosure of any item in any Section of this Disclosure Schedule will constitute disclosure for purposes of another Section if it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other Sections or Sub-Sections.

(c) Inclusion of any item in a Section of this Disclosure Schedule does not constitute a determination by the Company that such item is material and shall not be deemed to establish a standard or materiality. No disclosure in any Section of this Disclosure Schedule relating to any possible breach or violation of any agreement, law or any potential adverse contingency shall be construed as an admission or indication that any such breach or violation exists or has actually occurred or that such adverse contingency will actually occur.

(d) Any capitalized terms not defined in this Disclosure Schedule shall have the meanings assigned thereto in the Agreement. Any section headings or titles used herein are included for convenience only and shall not be considered as representations or warranties as to the type, character or content of the matters referred to thereunder.

**SUBSIDIARIES OF THE COMPANY**

1. Delcath Holdings Limited
2. Delcath Systems Limited
3. Delcath Systems UK Limited
4. Delcath Systems GmbH
5. Delcath Systems B.V.



**Organization and Qualification**

None.

Conflicts

None.

**Capitalization**

- A. Shares beneficially owned by Affiliates: 1,284,329
- B. 12.6 million shares issued since most recent periodic report

**Rights of Participation:**

September 2017 Hudson Bay and Alto

February 2018: Registered Direct Investors

June 2018: Discover Growth Fund, as assigned to Rosalind Master Fund LP by Discover Growth Fund as signatory to the Securities Purchase Agreement dated as of June 4, 2018.

Delcath Systems, Inc.

Capitalization Table as of April 22, 2019

	<u>Authorized</u>	<u>Issued</u>	<u>Treasury</u>	<u>Outstanding</u>
Preferred Shares	10,000,000	-	-	-
Common Shares	1,000,000,000	18,277,807	-	18,277,807
<b>Fully diluted common shares:</b>				
Feb 2015 Warrants (\$0.01; exp 2/2020)				9
July 2015 Warrants (\$0.01; exp 7/2020)				9
Oct 2016 Warrants (\$0.01; exp 10/2021)				11
Feb 2018 Warrants (\$10.00; exp 2/2024)				189,000
June 2018 Warrants (\$0.01, exp through 6/2024)				16,615,317
June 2018 Warrants (\$4.00; exp 6/2023)				1,116,256
July 2018 Warrants (\$0.01, exp through 7/2024)				12,168,926
July 2018 Warrants (\$4.00 exp 7/2023)				785,737
August 2018 Warrants (\$0.01, exp through 8/2024)				23,777,381
August 2018 Warrants (\$1.75; exp 8/2023)				2,021,410
Sep 2018 Warrants (\$0.01, exp through 9/2024)				830,854
Sep 2018 Warrants (\$1.75; exp 9/2023)				279,506
Options				1,250,000
<b>Total shares reserved for warrants and options</b>				<u>59,034,416</u>
<b>Total shares issued and reserved:</b>				<u><u>77,312,223</u></u>

**Corporate Governance of Delcath Systems, Inc.**

Roger Stoll, Ph.D., Chairman

William Rueckert

Dr. Marco Taglietti

Dr. Jennifer Simpson

Audit Committee – William Rueckert, Chair; Roger Stoll

Compensation Committee – Marco Taglietti, Chair; William Rueckert

Nominating and Corp. Governance Committee – Roger Stoll, Chair; William Rueckert; Marco Taglietti

**Indebtedness**

1. Letter of credit issued by Silicon Valley Bank to Kasowitz, Benson, Torres and Friedman LLP with face amount of \$130,663.00.
2. Letter of credit issued by Silicon Valley Bank to SLG 810 7th Avenue Lessee LLC with face amount of \$881,297.08.
3. Indebtedness in a maximum amount of \$75,000 owed to Silicon Valley Bank under corporate credit card services agreement.
4. Indebtedness between Delcath Systems, Inc. and Delcath Holdings Limited pursuant to a License and Agreement to Share Intangible Development Costs dated as of January 1, 2012.
5. Indebtedness of \$5,478,559 between Delcath Systems, Inc. and Rosalind Master Fund L.P., as assigned to Rosalind Master Fund LP by Discover Growth Fund and Discover Growth Fund, LLC as signatories to Securities Purchase Agreements dated as of June 4, 2018; July 20, 2018; August 29, 2018; and a Note Purchase and Exchange Agreement dated March 29, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
6. Indebtedness of \$469,975 between Delcath Systems, Inc. and the institutional investors signatory to Securities Purchase Agreements dated as of September 21, 2018 and the 8% Senior Secured Convertible Promissory Notes issued pursuant thereto.
7. Indebtedness of \$180,000 between Delcath Systems, Inc. and Rosalind Master Fund LP as signatory to the Securities Purchase Agreement dated as of April 18, 2019 and the 8% Senior Secured Promissory Note issued pursuant thereto.
8. Indebtedness of \$370,000 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$550,000 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of April 26, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
9. Indebtedness of \$550,000 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$550,000 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of May 9, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.

### **Existing Liens**

1. Liens of Silicon Valley Bank on account nos. 3301246486 and 3301264690, respectively, securing the letters of credit described in numbers 1 and 2 above.
2. Lien of Silicon Valley Bank account no. 3301464115 securing the Indebtedness described in number 3 above.
3. Lien of the institutional investor securing the Obligations described in numbers 5 -8 above.

**SEC Reports; Financial Statements**

The Company has not timely filed its Annual Report on Form 10-K or its Proxy Statement for the year ended December 31, 2018.

The Company will not timely file its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

**Material Changes; Undisclosed Events, Liabilities or Developments**

See Schedule 3.1(m).



**Litigation**

1. In March 2019, the Company sued two affiliated Iroquois Funds and FirstFire seeking declaratory judgment, among other remedies, that the February 2018 warrants issued to them are deemed to not including an “exploding” antidilution feature upon a down round financing. The suit was filed in New York State Supreme Court in NY County, NY.

See Schedule 3.1(m) below for any potential claims.

**Compliance**

UBC Demand Letter for \$2,106,116.00.

Payables to Roth Capital in the amount of \$552,642.60.

Notices of Default from Discover Growth Fund, Discover Growth Fund, LLC, Bigger Capital Fund, LP and District 2 Capital Fund LP in respect of the Indebtedness listed in paragraph 5 of Schedule 3.1(h).

Title to Assets

See Schedule 3.1(h).

**Material Agreements**

See Schedule 3.1(m).

Intellectual Property

None.

**Transactions with Affiliates and Employees**

Herein below are all back salaries and unreimbursed employee expenses through April 15, 2019:

Jennifer Simpson	\$	862,376
Barbra Keck	\$	536,181
John Purpura	\$	553,491
All other employees	\$	335,670
	\$	2,287,718

Cash Payments

None.

**Certain Fees**

Fees to Roth Capital Partners, LLC under waiver letter with Roth Capital Partners, LLC  
Fees to Think Equity under Engagement Letter



**Registration Rights**

Warrants issued in February 2018

September 21, 2018 Securities Purchase Agreement

Accountants

Marcum LLP

Grant Thornton LLP (with respect to 2015, 2016 and 2017 audited financials only)

Seniority

See Schedule 3.1(h).

Off-balance Sheet Arrangements

None.

**Investor Relations**

None.

Use of Proceeds

General working capital purposes.

**NOTE PURCHASE AGREEMENT**

This Note Purchase Agreement (this “Agreement”) is dated as of June 6, 2019, by and among Delcath Systems, Inc., a Delaware corporation (the “Company”), and the purchasers identified on the signature pages hereto (each, a “Purchaser”, or in the aggregate, the “Purchasers”).

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), Regulation S and Rule 506(b) promulgated thereunder, the Company desires to sell, and the Purchasers desire to purchase from the Company, the Notes (as defined herein).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

**ARTICLE I.  
DEFINITIONS**

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement: (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Transaction Documents (as defined herein), and (b) the following terms have the meanings set forth in this Section 1.1:

“Action” shall have the meaning ascribed to such term in Section 3.1(k).

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Approved Financing” means any equity financing or financings, to be completed no later than June 21, 2019, which results in gross cash proceeds to the Company of not less than \$20 million, and shall not, for greater certainty, include the conversion of the Company’s existing Indebtedness into Common Stock of the Company.

“BHCA” shall have the meaning ascribed to such term in Section 3.1(l).

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

“Closing Date” means the Trading Day(s) on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto in connection with a Closing, and all conditions precedent to (i) the Purchasers’ obligation to pay the Subscription Amount as to the Closing and (ii) the Company’s obligations to deliver the Notes as to the Closing, in each case, have been satisfied or waived.

“Closing” means closing of the purchase and sale of the Notes pursuant to Section 2.2.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Disclosure Schedules” shall have the meaning ascribed to such term in Section 3.1.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(t).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exchange Transaction” shall have the meaning ascribed to such term in Section 4.15(b).

“Exempt Issuance” means the issuance of (a) shares of Common Stock, restricted stock units or options to employees, officers, directors, advisors or independent contractors of the Company pursuant to any stock or option plan duly adopted for such purpose, (b) shares of Common Stock, warrants or options to advisors or independent contractors of the Company for compensatory purposes, (c) securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date hereof, provided that such securities have not been amended since the date hereof to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, (d) securities issuable pursuant to any contractual anti-dilution, most favored nations or similar obligations of the Company in effect as of the date hereof, provided that such obligations have not been materially amended since the date of hereof, and (e) securities issued pursuant to acquisitions or any other strategic transactions approved by the Board of Directors, provided that any such issuance shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“Federal Reserve” shall have the meaning ascribed to such term in Section 3.1(ll).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(i).

“Guarantors” mean collectively, the Subsidiaries of the Company who are party to the Subsidiary Guarantee.



“Indebtedness” means except for Permitted Indebtedness, (a) any liabilities for borrowed money or amounts owed in excess of \$100,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company’s consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of \$100,000 due under leases required to be capitalized in accordance with GAAP.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(q).

“Intellectual Property Security Agreement” means that certain Intellectual Property Security Agreement required to be delivered pursuant to Section 2.3 of this Agreement, in the form attached hereto as Exhibit B.

“Liabilities” means all direct or indirect liabilities, Indebtedness and obligations of any kind of Company to the Purchaser, howsoever created, arising or evidenced, whether now existing or hereafter arising (including those acquired by assignment), absolute or contingent, due or to become due, primary or secondary, joint or several, whether existing or arising through discount, overdraft, purchase, direct loan, participation, operation of law, or otherwise, including, but not limited to, pursuant to the Note, this Agreement and/or any of the other Transaction Documents, all accrued but unpaid interest on the Note, any letter of credit, any standby letter of credit, and/or outside attorneys’ and paralegals’ fees or charges relating to the preparation of the Transaction Documents and the enforcement of the Purchaser’s rights, remedies and powers under this Agreement, the Note and/or the other Transaction Documents.

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(n).

“Maximum Rate” shall have the meaning ascribed to such term in Section 5.17.

“Money Laundering Laws” shall have the meaning ascribed to such term in Section 3.1(qq).

“Notes” means, collectively, the 8% Senior Secured Promissory Notes issued by the Company to each Purchaser hereunder, each in the form of Exhibit A attached hereto.

“Off-balance Sheet Arrangement” shall have the meaning ascribed to such term in Section 3.1(pp).

“Penny Warrants” means, collectively, the 53,374,624 warrants to purchase shares of Common Stock with a strike price of \$0.01 per share, originally issued pursuant to the documents listed in Schedule 1.1(a).

“Permitted Indebtedness” means the letters of credit and secured accounts listed in Schedule 3.1(h).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Product” means the Company’s investigational product, Melphalan

Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, also known as CHEMOSAT.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.9.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(i).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Security Agreement” means the Security Agreement dated on the date hereof by and among the Company, the Company’s Subsidiaries, and the Purchaser, as hereinafter amended and/or supplemented altogether with all exhibits, schedules and annexes to such Security Agreement, pursuant to which all Liabilities of the Company to the Purchaser under the Transaction Documents are secured by the Collateral (as defined in the Security Agreement), which security interest in the Collateral shall be perfected by the Purchaser’s UCC-1, filed with the Secretary of State of the State of Delaware, to the extent perfectable by the filing of a UCC-1 Financing Statement, or if applicable, a UCC-3 Financing Statement Amendment and such other documents and instruments related thereto, which Security Agreement is annexed hereto as Exhibit C.

“Shell Company” means an entity that fits within the definition of “shell company” under Section 12b-2 of the Exchange Act and Rule 144.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act.

“Straight Warrants” means, collectively, the 1,901,993 warrants to purchase shares of Common Stock with a strike price of \$4.00 per share and 2,021,410 warrants to purchase shares of Common Stock with a strike price of \$1.75 per share, originally issued pursuant to the documents listed in Schedule 1.1(b).

“Subscription Amount” means \$2,000,000.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Subsidiary Guarantee” means the Subsidiary Guarantee, dated as of the date hereof, pursuant to which the Subsidiaries have jointly and severally agreed to guarantee and act as surety for the Company’s obligation to repay the Notes, in the form attached hereto as Exhibit D.

“Third Party Exchange Transfer” shall have the meaning ascribed to such term in Section 4.14(b).

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; OTC Markets or the OTC Bulletin Board (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Notes, the Security Agreement, the Intellectual Property Security Agreement, the Subsidiary Guarantee and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Variable Rate Transaction” shall have the meaning ascribed to such term in Section 4.14(a).

“Warrants” means, collectively, the Penny Warrants and the Straight Warrants.

1.2 Currency. All dollar amounts in this Agreement refer to U.S. dollars;

**ARTICLE II.  
PURCHASE AND SALE**

2.1 Purchase. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company shall sell and issue to each Purchaser, and each Purchaser shall purchase, severally and not jointly, from the Company, Notes with an aggregate principal amount of \$2,000,000. The purchase of the Notes will be completed in a single tranche as provided herein.

2.2 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and each Purchaser agrees to purchase, the Subscription Amount of Notes as set forth on the signature page hereto executed by such Purchaser. At the Closing, each Purchaser shall transfer and surrender for cancellation the Warrants held by such Purchaser to the Company in full payment and satisfaction of the Subscription Amount, and the Company shall deliver to such Purchaser its Notes as set forth in Section 2.3(a), and the Company and such Purchaser shall deliver the other items set forth in Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4 for Closing, such Closing shall be undertaken remotely by electronic exchange of Closing documentation.

2.3 Deliveries.

(a) On or prior to the Closing Date (except as otherwise agreed by the Purchaser), the Company shall deliver or cause to be delivered to each Purchaser the following:

- (i) this Agreement duly executed by the Company;
- (ii) the Notes;
- (iii) the Security Agreement, duly executed by the Company;
- (iv) the Intellectual Property Security Agreement, duly executed by the Company;
- (v) the Subsidiary Guarantee, duly executed by the Company's Subsidiaries;
- (vi) [Reserved];
- (vii) the opinion of McCarter & English LLP, the Company's counsel, dated as of the Closing Date;
- (viii) [Reserved];
- (ix) a certificate evidencing the Company's qualification as a foreign corporation and good standing issued by the Secretary of State (or comparable office) of each jurisdiction, if any, in which the Company conducts business and is required to so qualify, as of a date within ten (10) days of the Closing Date;

(x) a certificate executed by the Secretary of the Company and dated as of the Closing Date, as to (i) the resolutions, as adopted by the Board of Directors in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of this Agreement and the other Transaction Documents and the issuance, offering and sale of the Notes and (B) the performance of the Company of its obligations under the Transaction Documents contemplated therein, (ii) referencing links to the Company's amended and restated certificate of incorporation, as amended, (iii) referencing links to the Company's amended and restated by-laws, each as in effect at the Closing and (iv) attaching a certificate of incumbency;

(xi) a certificate executed by the Secretary of the each Guarantor and dated as of the Closing Date, as to (i) the resolutions, as adopted by the board of directors of such Guarantor in a form reasonably acceptable to the Purchasers, approving (A) the entering into and performance of Transaction Documents to which it is a party and (B) the performance of Guarantor of its obligations under the Transaction Documents to which it is a party contemplated therein, (ii) referencing links to Guarantor's constating documents and (iii) attaching a certificate of incumbency; and

(xii) such other documents, instruments or certificates relating to the transactions contemplated by this Agreement as such Purchaser or its counsel may reasonably request.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, as applicable, the following:

(i) this Agreement, duly executed by the Purchaser;

(ii) an executed instrument of transfer of the Warrants held by such Purchaser in such form as the Company may reasonably require;

(iii) the Security Agreement, duly executed by the Purchaser; and

(iv) the Intellectual Property Security Agreement, duly executed by the Purchaser.

#### 2.4 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects as at Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by the Purchaser of the items set forth in Section 2.3(b) of this Agreement.

(b) The respective obligations of each Purchaser hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects when made as to the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.3(a) of this Agreement;

(iv) there is no existing Event of Default (as defined in the Notes) and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default;

(v) there is no breach of any obligations, covenants and agreements under the Transaction Documents and no existing event which, with the passage of time or the giving of notice, would constitute a breach under the Transaction Documents;

(vi) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;

(vii) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of the Purchaser, and without regard to any factors unique to the Purchaser, makes it impracticable or inadvisable to purchase the Notes at the Closing;

(viii) an Approved Financing shall have been consummated, or the Purchaser shall otherwise be satisfied, in its sole discretion, that an Approved Financing will be consummated concurrently with the Closing hereunder;

(ix) the text and timing of any public announcement or filing with any governmental authority or stock exchange by the Company of the transactions contemplated hereby following execution of this Agreement shall be approved in writing by the Purchasers, acting reasonably, in advance of such announcement or filing being made; and

(x) any other conditions contained herein or the other Transaction Documents, including, without limitation those set forth in Section 2.3 herein.

### **ARTICLE III. REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. Except as set forth in the disclosure schedules attached hereto (the “Disclosure Schedules”), which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company (which for purposes of this Section 3.1 means the Company and all of its Subsidiaries) hereby makes the following representations and warranties to each Purchaser as of the Closing Date:

(a) Subsidiaries. All of the direct and indirect Subsidiaries and parent entities of the Company are set forth on Schedule 3.1(a) hereto. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, other than as set forth on Schedule 3.1(a) hereto, and all of the issued and outstanding shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized and validly existing, and, other than as set forth on Schedule 3.1(b) hereto, the Company is in good standing, under the laws of the jurisdiction of its incorporation or organization, as applicable, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary or parent entity of the Company is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document; (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company, its parent entities and the Subsidiaries, taken as a whole; or (iii) a material adverse effect on the Company’s ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a “Material Adverse Effect”) and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Notes and the consummation by it of the transactions contemplated hereby and thereby do not and will not, except as set forth on Schedule 3.1(d): (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents; (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien (except Liens in favor of the Purchaser) upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected; or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.13 of this Agreement; (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Notes in the time and manner required thereby; and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").



(f) Issuance of the Notes. The Notes are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents.

(g) Capitalization; Corporate Governance.

(i) The capitalization of the Company is as set forth on Schedule 3.1(g)(i), which Schedule 3.1(g)(i) shall also include (A) the number of shares of Common Stock owned beneficially, and of record, by Affiliates of the Company as of the date hereof and (B) the number of authorized and reserved shares of capital stock of the Company. The Company has not issued capital stock since its most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i), except the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and except pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act except as set forth on Schedule 3.1(g)(i). No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents except as set forth on Schedule 3.1(g)(i). There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents except as set forth on Schedule 3.1(g)(i). The issuance and sale of the Notes will not obligate the Company to issue shares of Common Stock or other securities to any Person and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities except as set forth on Schedule 3.1(g)(i). All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Notes. There are no stockholders' agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(ii) The names and titles of each of the Company's principal officers, directors and beneficial holders of at least five percent (5%) of the outstanding shares of each class of the Company's capital stock on a fully diluted basis are as set forth on Schedule 3.1(g)(ii), which Schedule 3.1(g)(ii) shall also include each committee of directors as well as the names and titles of each director currently serving on each such committee.

(h) Indebtedness. Schedule 3.1(h) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Except as set forth on Schedule 3.1(h), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(i) SEC Reports; Financial Statements. Other than as set forth on Schedule 3.1(i) hereto, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”). As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the Company’s Annual Report on Form 10-K, including such latest audited financial statements, or in a subsequent SEC Report filed prior to the date hereof and except as set forth in Schedule 3.1(g), Schedule 3.1(m), and Schedule 3.1(j): (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect; (ii) the Company has not incurred any liabilities or obligations (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in filings made with the Commission; (iii) the Company has not altered its method of accounting; (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock; (v) the Company has not sold, assigned or transferred any other tangible assets or Intellectual Property Rights, or canceled any debts or claims, except in the

ordinary course of business, (vi) the Company has not suffered any substantial loss contingencies or waived any rights of material value, whether or not in the ordinary course of business, or suffered the loss of any material amount of prospective business, (vii) the Company has not entered into any acquisition or financing transactions, whether or not in the ordinary course of business, other than with respect to the Transaction Documents and (v) the Company has not issued any equity securities to any officer, director or Affiliate, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties except as set forth in Schedule 3.1(k), or against or affecting the Company's current or former officers or directors in their capacity as such, before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Notes or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect, and neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company that is likely to lead to action that can reasonably be expected to result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition

agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary, except as set forth in Schedule 3.1(m): (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived); (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority; or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except as set forth in Schedule 3.1(o) and except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance.

(p) Material Agreements. Except for the Transaction Documents (with respect to clause (i) only) or as set forth on Schedule 3.1(p) hereto, or as would not be reasonably likely to have a Material Adverse Effect, (i) the Company and each of its Subsidiaries have performed all obligations required to be performed by them to date under any written or oral contract, instrument, agreement, commitment, obligation, plan or arrangement, filed or required to be filed with the Commission (the "Material Agreements"), (ii) neither the Company nor any of its Subsidiaries has received any notice of default under any Material Agreement and, (iii) to the best of the Company's knowledge, neither the Company nor any of its Subsidiaries is in default under any Material Agreement now in effect.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as necessary or required for use in connection with their respective businesses as presently conducted and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or could not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights except as disclosed in Schedule 3.1(q). The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) Transactions with Affiliates and Employees. Except as disclosed in Schedule 3.1(r), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from providing for the borrowing of money from or lending of money to, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for: (i) payment of salary or consulting fees for services rendered; (ii) reimbursement for expenses incurred on behalf of the Company; and (iii) other employee benefits.

(s) Payments of Cash. Except as disclosed on Schedule 3.1(s), neither the Company, its directors or officers, or any Affiliates or agents of the Company, have withdrawn or paid cash to any vendor in an aggregate amount that exceeds \$5,000 for any purpose.

(t) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(u) Certain Fees. Other than as set forth on Schedule 3.1(u), no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiaries to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchaser shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(v) Private Placement. Assuming the accuracy of each Purchaser's representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Notes by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Notes hereunder does not contravene the rules and regulations of the Trading Market.

(w) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Notes, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(x) Registration Rights. Other than as set forth on Schedule 3.1(x) and pursuant to this Agreement, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiaries.

(y) Listing and Maintenance Requirements; Trading Market Regulation. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC reports, the Company has not, in the twelve (12) months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements.

(z) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's amended and restated certificate of incorporation, as amended (or similar charter documents), or the laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Notes and the Purchasers' ownership of the Notes.

(aa) Disclosure. All of the disclosure furnished by or on behalf of the Company to the Purchaser regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The press releases

disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(bb) No Integrated Offering. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Notes to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(cc) No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Notes by any form of general solicitation or general advertising. The Company has offered the Notes for sale only to the Purchaser and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds; (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law; or (iv) violated in any material respect any provision of FCPA.

(ee) Accountants. The Company's accounting firm is set forth on Schedule 3.1(ee). To the knowledge and belief of the Company, such accounting firm is a registered public accounting firm as required by the Exchange Act.

(ff) No Disagreements with Accountants and Lawyers. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.



(gg) Acknowledgment Regarding Purchaser's Purchase of the Notes. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by the Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Notes. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Notes, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, the Notes, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the Notes.

(ii) Stock Option Plans. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their respective financial results or prospects.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Promotional Stock Activities. Neither the Company, its officers, its directors, nor any affiliates or agents of the Company have engaged in any stock promotional activity that could give rise to a complaint, inquiry, or trading suspension by the Commission alleging (i) a violation of the anti-fraud provisions of the federal securities laws, (ii) violations of the anti-touting provisions, (iii) improper “gun-jumping”; or (iv) promotion without proper disclosure of compensation.

(nn) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(oo) Seniority. As of the Closing Date, other than as set forth on Schedule 3.1(oo), no Indebtedness or other claim against the Company is senior to the Notes in right of payment, whether with respect to interest or upon liquidation or dissolution, or otherwise, other than indebtedness secured by purchase money security interests (which is senior only as to underlying assets covered thereby) and capital lease obligations (which is senior only as to the property covered thereby).

(pp) No “Off-balance Sheet Arrangements”. Other than as set forth in Schedule 3.1(pp), neither the Company nor any of its Affiliates is involved in any “Off-balance Sheet Arrangements”. For purposes hereof an “Off-balance Sheet Arrangement” means any transaction or contract to which an entity unconsolidated with the Company or any of its Affiliates is a party and under which either the Company or any such Affiliate has: (i) any obligation under a guarantee contract pursuant to which the Company or any of its Affiliates could be required to make payments to the guaranteed party, including any standby letter of credit, market value guarantee, performance guarantee, indemnification agreement, keep-well or other support agreement; (ii) any retained or contingent interest in assets transferred to such unconsolidated entity that serves as credit, liquidity or market risk support to the entity in respect of such assets; (iii) any variable interest held in such unconsolidated entity where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with the Company or any of its Affiliates; and (iv) any liability or obligation of the same nature as those described in clauses (i) through (iii) of this sentence even if of a different name (whether absolute, accrued, contingent or otherwise) that would not be required to be reflected in the Company or any of its Affiliates’ financial statements.

(qq) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the “Money Laundering Laws”), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(rr) Subsidiary Rights. The Company has the unrestricted right to vote, and (subject to limitations imposed by applicable law) to receive dividends and distributions on, all capital securities of each of its Subsidiaries as owned by the Company or any Subsidiary.

(ss) Shell Company Status. The Company has never been, and is not presently, an issuer identified as a Shell Company.

(tt) Investor Relations. Other than as set forth in Schedule 3.1(tt), the Company is not currently a party, nor does it intend to become a party, to any agreement pursuant to which the Company will receive investor relations services.

(uu) Full Disclosure. No representation or warranty by the Company in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to the Purchasers pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

(vv) No Bad Actor Disqualification Event. After reasonable inquiry, none of the “Bad Actor” disqualifying events described in Rule 506(d)(1) under the Securities Act (a “Disqualification Event”) is applicable to Company or to Company’s knowledge any of its Affiliates, except a Disqualification Event as to which Rule 506(d)(2)(iii) applies.

(ww) Company has not, and will not, engage in any directed selling efforts in the United States in respect of the Notes. Company is offering and selling the Notes only to non U.S. Persons, in compliance with the offering restriction requirements of Regulation S.

3.2 Representations and Warranties of the Purchaser. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein in which case they shall be accurate as of such date):

(a) Organization; Authority. The Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by the Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. The Purchaser understands that the Note is a "restricted security" and has not been registered under the Securities Act or any applicable state securities law and is acquiring the Note as principal for its own account (this representation and warranty not limiting the Purchaser's right to sell the Note in compliance with applicable federal and state securities laws). The Purchaser is acquiring the Note hereunder in the ordinary course of its business.

(c) Purchaser Status. At the time the Purchaser was offered the Note, it was, and as of the date hereof it is an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act.

(d) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Note, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Note and, at the present time, is able to afford a complete loss of such investment.

(e) General Solicitation. The Purchaser is not purchasing the Note as a result of any advertisement, article, notice or other communication regarding the Note published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

- (f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, the Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of the Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of the Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Note covered by this Agreement. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).
- (g) Non U.S. Person. The Purchaser is not a "U.S. Person" as that term is defined in Regulation S under the Securities Act, and is not acquiring the Note for the account or beneficial ownership of any U.S. Person.
- (h) No Short Sales. Neither Purchaser nor any Affiliate of Purchaser (i) holds any short position in the Common Stock, (ii) has ever engaged in, directly or indirectly, any Short Sale of the Common Stock, or (iii) has ever engaged in, directly or indirectly, any hedging transaction with regard to the Common Stock.
- (i) Not a Bad Actor. After reasonable inquiry, none of the "Bad Actor" disqualifying events described in Rule 506(d) (l) under the Securities Act is applicable to the Purchaser or any of its Affiliates. The Purchaser is not now, and has never been, subject to any final cease and desist order or any penalty from the Commission or any court of competent jurisdiction for any violation of any provision of the Securities Act or the Exchange Act, or any of the regulations promulgated thereunder.
- (j) Not an Affiliate. The Purchaser is not now, and has never been, an Affiliate of the Company or any other Purchaser. The Purchaser is not now, and has never been, part of any group of Persons that would be required under Section 13(d) of the Exchange Act, or the rules and regulations promulgated thereunder, to file a statement on Schedule 13D or Schedule 13G with regard to the Company.
- (k) Warrants. The Purchaser is the legal and beneficial owner of the Warrants, free and clear of any lien, encumbrance or other adverse claim of any nature.

The Company acknowledges and agrees that the representations contained in Section 3.2 shall not modify, amend or affect the Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transaction contemplated hereby.

**ARTICLE IV.  
OTHER AGREEMENTS OF THE PARTIES**

4.1 Transfer Restrictions.

(a) The Notes may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of the Notes other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, at the Company's sole expense in the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of the Notes under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchaser agrees to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Notes in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON REGULATION S OR AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO REGULATION S OR AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

The Company acknowledges and agrees that the Purchaser may from time to time pledge, pursuant to a bona fide margin agreement with a registered broker-dealer, or grant a security interest in some or all of the Notes to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and who agrees to be bound by the provisions of this Agreement and, if required under the terms of such arrangement,

the Purchaser may transfer the Notes to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the Company's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of the Notes may reasonably request in connection with a pledge or transfer of the Notes.

4.2 [Reserved].

4.3 [Reserved].

4.4 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Notes in a manner that would require the registration under the Securities Act of the sale of the Notes or that would be integrated with the offer or sale of the Notes for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.5 [Reserved].

4.6 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an "acquiring person" or such similar term under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving the Notes under the Transaction Documents or under any other agreement between the Company and the Purchaser.

4.7 [Reserved].

4.8 Use of Proceeds. The Company shall use the net proceeds as set forth in Schedule 4.8.

4.9 Indemnification of Purchaser. Subject to the provisions of this Section 4.9, the Company will indemnify and hold the Purchaser and its directors, officers, managers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, managers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any the Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any

of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based in whole or in part upon a breach of the Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings the Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by the Purchaser Party which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of the Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (x) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (y) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.9 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnification contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10 [Reserved].

4.11 Certain Transactions. The Purchaser covenants and agrees that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any Short Sales of the Common Stock or hedging transaction, which establishes a net short position with respect to the Company's Common Stock) during the period commencing with the execution of this Agreement and ending on the earlier of the Maturity Date (as defined in the Notes) of the Notes or the full repayment of the Notes; provided that this provision shall not operate to restrict a Purchaser's trading under any prior securities purchase agreement containing contractual rights that explicitly protects such trading in respect of the previously issued securities.



4.12 Securities Laws Disclosure; Publicity. The Company and the Purchaser shall consult with each other in issuing any public disclosure with respect to the transactions contemplated hereby, and neither the Company nor the Purchaser shall issue any such public disclosure nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law or rules of the principal Trading Market, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of the Purchaser, or include the name of the Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of the Purchaser, except: (a) as required by federal securities law in connection with any registration statement contemplated by this Agreement and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchaser with prior notice of such disclosure permitted under this clause (b).

4.13 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Note as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Notes for, sale to the Purchaser at the Closing under applicable securities or “Blue Sky” laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

4.14 Subsequent Equity Sales.

(a) For so long as any of the Notes remain outstanding, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. “Variable Rate Transaction” means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price.

(b) For as long as any of the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will (without the prior written consent of the Purchaser), directly or indirectly: (a) solicit, initiate, encourage or accept any other inquiries, proposals or offers from any Person relating to any exchange (i) of any security of the Company or any of its Subsidiaries for any other security of the Company or any of its Subsidiaries, except to the extent (x) consummated pursuant to the terms of Common Share Equivalents of the Company as in effect as of the date hereof and disclosed in filings with the Commission prior to the date hereof (without giving effect to any amendment, modification, change or waiver of any terms thereof occurring on or after the date hereof or not disclosed in a filing by the Company with the Commission prior to the date hereof) or (ii) of any indebtedness or other securities of, or claim against, the Company or any of its Subsidiaries pursuant to a registration statement filed with the Commission or relying on any exemption under the Securities Act (including, without limitation, Section 3(a)(10) of the Securities Act (any such transaction described in clauses (i) or (ii), an “Exchange Transaction”); (b) enter into, effect, alter, amend, announce or recommend to its stockholders any Exchange Transaction with any Person; or (c) participate in any discussions, conversations, negotiations or other communications with any Person regarding any Exchange Transaction, or furnish to any Person any information with respect to any Exchange Transaction, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to seek an Exchange Transaction involving the Company or any of its Subsidiaries. For as long as the Notes remain outstanding, neither the Company nor any of its affiliates or Subsidiaries, nor any of its or their respective officers, employees, directors, agents or other representatives, will, directly or indirectly, cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any Person to effect any acquisition of securities or indebtedness of, or claim against, the Company by such Person from an existing holder of such securities, indebtedness or claim in connection with a proposed exchange of such securities or indebtedness of, or claim against, the Company (whether pursuant to Section 3(a)(9) or 3(a)(10) of the Securities Act or otherwise) (a “Third Party Exchange Transfer”). The Company, its affiliates and Subsidiaries, and each of its and their respective officers, employees, directors, agents or other representatives shall immediately cease and cause to be terminated all existing discussions, conversations, negotiations and other communications with any Persons with respect to any of the foregoing. For all purposes of this Agreement, violations of the restrictions set forth in this Section 4.14 by any Subsidiary or affiliate of the Company, or any officer, employee, director, agent or other representative of the Company or any of its Subsidiaries or affiliates shall be deemed a direct breach of this Section 4.14 by the Company.

(c) From the date hereof until sixty (60) calendar days after the Closing Date, neither the Company nor any Subsidiary shall, directly or indirectly, except with respect to the proposed \$20,000,000 private investment in public equities contemplated to be completed by May 31, 2019, and as otherwise permitted under this Agreement, issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security (including, without limitation, any “equity security” (as that term is defined under Rule 405 promulgated under the Securities Act), any Common Shares or Common Share Equivalents, any debt securities, any preferred stock or any purchase rights) or otherwise amend, modify, waiver or alter any terms of conditions of any Common Share Equivalents outstanding as of the date hereof to decrease the exercise, conversion and/or exchange price, as applicable, thereunder or otherwise increase the aggregate number of Common Shares issuable in connection therewith.

(d) The Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding the foregoing, this Section 4.14 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.15. Regulation S Compliance. Each Purchaser agrees that, during the six (6) months following the Closing, it shall not engage in any transaction involving any securities of the Company that would be prohibited or restricted by, or would otherwise render unavailable any applicable safe harbor provided by Regulation S.

4.16 Proceeds of Commercial Arrangements. Upon receipt by the Company or any of its Subsidiaries of any payment, royalty payment or other consideration relating to, or under the terms of, any strategic partnership, joint venture, distribution, distributor, sales or other commercial arrangement or agreement related to the distribution, sale, promotion or regulatory approval of the Product, the Company shall forthwith (and in any event, within **[3]** days) give written notice of such receipt to the Purchasers. Each Purchaser may, at any time within **[10]** Business Days of receipt of such notice from the Company, elect to require that all or any portion of the cash value of such payment or other consideration be used to repay amounts outstanding under such Notes, and within **[3]** Business Days of such election being made by such Purchaser(s), the Company shall repay the applicable Notes in the amount specified by such Purchaser(s); provided that if more than one Purchaser gives such written notice then the Company shall repay the applicable Purchasers on a pro rata basis (based on the outstanding principal amount owing on the applicable Notes at the time of any such payment).

4.17 Waiver. Upon the satisfaction of each of the conditions precedent set out herein and concurrently with the consummation of the Closing hereunder, the Purchasers agree to waive all Events of Default (as defined in the Notes) of the Company and confirm that the Company shall not be restricted from redeeming all of the Penny Warrants in accordance with the terms thereof.

4.18 Public Announcement. The Company and the Purchasers agree to co-operate in the preparation of any public filing or announcement regarding the transactions contemplated by this Agreement, and the Company shall not (a) issue any press release or otherwise make public announcements with respect to this Agreement without the prior written consent of the Purchasers (which consent shall not be unreasonably withheld or delayed), or (b) make any filing with any governmental authority or stock exchange with respect thereto without the prior written consent of the Purchasers; provided, however, that the foregoing shall be subject to the Company's and the Purchasers' overriding obligation to make any disclosure or filing required under applicable law or stock exchange rules, and the party making such disclosure shall use commercially reasonable efforts to give prior oral or written notice to the other party and reasonable opportunity to review or comment on the disclosure or filing.

## **ARTICLE V. MISCELLANEOUS**

5.1 Termination. This Agreement may be terminated by the Purchaser, as to the Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before June 21, 2019; provided, however, that such termination will not affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. The Company has agreed to bear all fees, disbursements, and expenses in connection with the transactions contemplated herein, including, without limitation, the Company's legal and accounting fees and disbursements, the costs incident to the preparation, printing and distribution of any registration statement, filing fees, UCC fees, and costs associated with the Intellectual Property Security Agreement. The Company shall pay all stamp taxes and other taxes and duties levied in connection with the delivery of the Notes to the Purchasers in connection with the transactions contemplated hereby.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties hereto acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries to be provided by the Purchaser hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, New York 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Purchaser delivered in accordance with this Section 5.4. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service addressed to each Purchaser at the email address, facsimile number, or address of the Purchaser appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Purchaser. Any notice or other communication or deliveries hereunder shall be deemed

given and effective on the earliest (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers holding at least 50.1% in interest of the Notes then outstanding or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any amendment effected in accordance with accordance with this Section 5.5 shall be binding upon each Purchaser and holder of the Note and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 No Assignment. No party may assign this Agreement or any rights or obligations hereunder.

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Sections 4.9 and 5.5.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or

proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Notes.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever the Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then the Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of the Notes. If any of the Notes is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new Note, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new Note under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Note.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to the Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Usury. To the extent it may lawful do so, the Company hereby agrees not to insist upon or plead or in any manner whatsoever claim, and will resist any and all efforts to be compelled to take the benefit or advantage of, usury laws wherever enacted, now or at any time hereafter in force, in connection with any claim, action or proceeding that may be brought by the Purchaser in order to enforce any right or remedy under any Transaction Document. Notwithstanding any provision to the contrary contained in any Transaction Document, it is expressly agreed and provided that the total liability of the Company under the Transaction Documents for payments in the nature of interest shall not exceed the maximum lawful rate authorized under applicable law (the "Maximum Rate"), and, without limiting the foregoing, in no event shall any rate of interest or default interest, or both of them, when aggregated with any other sums in the nature of interest that the Company may be obligated to pay under the Transaction Documents exceed such Maximum Rate. It is agreed that if the maximum contract rate of interest allowed by law and applicable to the Transaction Documents is increased or decreased by statute or any official governmental action subsequent to the date hereof, the new maximum contract rate of interest allowed by law will be the Maximum Rate applicable to the Transaction Documents from the effective date thereof forward, unless such application is precluded by applicable law. If under any circumstances whatsoever, interest in excess of the Maximum Rate is paid by the Company to the Purchaser with respect to indebtedness evidenced by the Transaction Documents, such excess shall be applied by the Purchaser to the unpaid principal balance of any such indebtedness or be refunded to the Company, the manner of handling such excess to be at the Purchaser's election.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been cancelled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL**. **IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

*[Signature Pages Follow]*



IN WITNESS WHEREOF, the parties hereto have caused this Note Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**DELCATH SYSTEMS, INC.**

Address for Notice:

By: \_\_\_\_\_  
Name:  
Title:

1633 Broadway  
Suite 22C  
New York, New York 10019  
Attention: Barbra Keck  
E-Mail: [bkeck@delcath.com](mailto:bkeck@delcath.com)

With a copy to (which shall not constitute notice):

McCarter & English

100 Mulberry Street, Four Gateway Center  
Newark, New Jersey 07102  
Attention: David Broderick  
E-Mail: [dbroderick@mccarter.com](mailto:dbroderick@mccarter.com)

**[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]**

[PURCHASER SIGNATURE PAGES TO DELCATH SYSTEMS, INC. NOTE PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Note Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: Rosalind Master Fund LP

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:

\_\_\_\_\_

Title of Authorized Signatory:

\_\_\_\_\_

Email Address of Authorized Signatory:

\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount: \$1,000,000

Name of Purchaser: Rosalind Opportunities Fund I

Signature of Authorized Signatory of  
Advisor (Rosalind Advisors, Inc.) of Purchaser:

\_\_\_\_\_

Name of Authorized Signatory:

\_\_\_\_\_

Title of Authorized Signatory:

\_\_\_\_\_

Email Address of Authorized Signatory:

\_\_\_\_\_

Address for Notice to Purchaser:

175 Bloor Street East  
Suite 1316, North Tower  
Toronto, ON M4W 3R8  
Canada

Subscription Amount: \$1,000,000

**EXHIBIT A**

**Form of Senior Secured Promissory Notes**

**EXHIBIT B**

**Form of Intellectual Property Security Agreement**

**EXHIBIT C**

**Form of Security Agreement**

**EXHIBIT D**

**Form of Subsidiary Guarantee**

**DISCLOSURE SCHEDULES TO THE**

**NOTE PURCHASE AGREEMENT**

**BY AND AMONG DELCATH SYSTEMS, INC. AND  
THE PURCHASERS SIGNATORY THERETO**

**DATED June 6, 2019**

These Sections (these “**Sections**”) of this Disclosure Schedule are numbered to correspond to the corresponding sections of the Note Purchase Agreement (the “**Agreement**”). These Sections have been prepared in accordance with, and subject to, the following terms and conditions:

- (a) To the extent a Section is intended to qualify a representation or warranty of the Company contained in the Article III of the Agreement, the information and disclosures contained in such Section are intended only to qualify and limit such representation or warranty and not in any way expand the scope or effect of such representation or warranty.
- (b) The disclosure of any item in any Section of this Disclosure Schedule will constitute disclosure for purposes of another Section if it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other Sections or Sub-Sections.
- (c) Inclusion of any item in a Section of this Disclosure Schedule does not constitute a determination by the Company that such item is material and shall not be deemed to establish a standard or materiality. No disclosure in any Section of this Disclosure Schedule relating to any possible breach or violation of any agreement, law or any potential adverse contingency shall be construed as an admission or indication that any such breach or violation exists or has actually occurred or that such adverse contingency will actually occur.
- (d) Any capitalized terms not defined in this Disclosure Schedule shall have the meanings assigned thereto in the Agreement. Any section headings or titles used herein are included for convenience only and shall not be considered as representations or warranties as to the type, character or content of the matters referred to thereunder.

**PENNY WARRANTS**

- Warrant to Purchase Common Stock no. D-1-201 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-202 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-203 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-204 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-205 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-206 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-207 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-208 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-209 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-210 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-211 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-212 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-1-213 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-2-201 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-202 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-203 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-204 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-205 issued on July 20, 2018 and issued by Delcath Systems Inc.;



- Warrant to Purchase Common Stock no. D-2-206 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-207 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-208 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-209 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-210 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-211 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-212 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-2-213 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-3-301 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-302 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-303 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-304 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-305 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-306 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-307 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-308 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-309 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-310 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-311 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-3-312 issued on August 29, 2018 and issued by Delcath Systems, Inc.;

- Warrant to Purchase Common Stock no. D-3-313 issued on August 29, 2018 and issued by Delcath Systems, Inc.;
- First Amendment to Warrants to Purchase Common Stock dated July 20, 2018 between Delcath Systems, Inc. and Discover Growth Fund, amending warrant nos. D-1-101 (with respect to changes 1. (b) and (d) only), D-1-201, D-1-202, D-1-203, D-1-204, D-1-205, D-1-206, D-1-207, D-1-208, D-1-209, D-1-210, D-1-211, D-1-212 and D-1-213; and
- Second Amendment to Warrant to Purchase Common Stock dated August 29, 2018 between Delcath Systems, Inc. and Discover Growth Fund, LLC, amending warrant nos. D-1-201 et. seq. and D-2-201 et seq.

**STRAIGHT WARRANTS**

- Warrant to Purchase Common Stock no. D-1-101 issued on June 4, 2018 and issued by Delcath Systems, Inc.;
- Warrant to Purchase Common Stock no. D-2-101 issued on July 20, 2018 and issued by Delcath Systems Inc.;
- Warrant to Purchase Common Stock no. D-3-101 issued on August 29, 2018 and issued by Delcath Systems Inc.;

**SUBSIDIARIES OF THE COMPANY**

1. Delcath Holdings Limited
2. Delcath Systems Limited
3. Delcath Systems UK Limited
4. Delcath Systems GmbH
5. Delcath Systems B.V.

**Organization and Qualification**

None.

Conflicts

None.

Capitalization

- A. Shares beneficially owned by Affiliates: 1,284,329  
 B. 12.6 million shares issued since most recent periodic report

## Rights of Participation:

September 2017 Hudson Bay and Alto

February 2018: Registered Direct Investors

June 2018: Discover Growth Fund, as assigned to Rosalind Master Fund LP by Discover Growth Fund as signatory to the Securities Purchase Agreement dated as of June 4, 2018.

Delcath Systems, Inc.

Capitalization table as of April 22, 2019

	<u>Authorized</u>	<u>Issued</u>	<u>Treasury</u>	<u>Outstanding</u>
Preferred Shares	10,000,000	-	-	-
Common Shares	1,000,000,000	18,277,807	-	18,277,807
Fully diluted common shares:				
Feb 2015 Warrants (\$0.01; exp 2/2020)				9
July 2015 Warrants (\$0.01; exp 7/2020)				9
Oct 2016 Warrants (\$0.01; exp 10/2021)				11
Feb 2018 Warrants (\$10.00; exp 2/2024)				189,000
June 2018 Warrants (\$0.01, exp through 6/2024)				16,615,317
June 2018 Warrants (\$4.00; exp 6/2023)				1,116,256
July 2018 Warrants (\$0.01, exp through 7/2024)				12,168,926
July 2018 Warrants (\$4.00 exp 7/2023)				785,737
August 2018 Warrants (\$0.01, exp through 8/2024)				23,777,381
August 2018 Warrants (\$1.75; exp 8/2023)				2,021,410
Sept 2018 Warrants (\$0.01, exp through 9/2024)				830,854
Sept 2018 Warrants (\$1.75; exp 9/2023)				279,506
Options				<u>1,250,000</u>
<b>Total shares reserved for warrants and options</b>				<b>59,034,416</b>
<b>Total shares issued and reserved:</b>				<u><b>77,312,223</b></u>

**Corporate Governance of Delcath Systems, Inc.**

Roger Stoll, Ph.D., Chairman

William Rueckert

Dr. Marco Taglietti

Dr. Jennifer Simpson

Audit Committee – William Rueckert, Chair; Roger Stoll, Marco Taglietti

Compensation Committee – Marco Taglietti, Chair; William Rueckert, Roger Stoll

Nominating and Corp. Governance Committee – Roger Stoll, Chair; William Rueckert; Marco Taglietti



Indebtedness

1. Letter of credit issued by Silicon Valley Bank to Kasowitz, Benson, Torres and Friedman LLP with face amount of \$130,663.00.
2. Letter of credit issued by Silicon Valley Bank to SLG 810 7th Avenue Lessee LLC with face amount of \$881,297.08.
3. Indebtedness in a maximum amount of \$75,000 owed to Silicon Valley Bank under corporate credit card services agreement.
4. Indebtedness between Delcath Systems, Inc. and Delcath Holdings Limited pursuant to a License and Agreement to Share Intangible Development Costs dated as of January 1, 2012.
5. Indebtedness of \$5,478,559 between Delcath Systems, Inc. and Rosalind Master Fund L.P., as assigned to Rosalind Master Fund LP by Discover Growth Fund and Discover Growth Fund, LLC as signatories to Securities Purchase Agreements dated as of June 4, 2018; July 20, 2018; August 29, 2018; and a Note Purchase and Exchange Agreement dated March 29, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
6. Indebtedness of \$469,975 between Delcath Systems, Inc. and the institutional investors signatory to Securities Purchase Agreements dated as of September 21, 2018 and the 8% Senior Secured Convertible Promissory Notes issued pursuant thereto.
7. Indebtedness of \$180,000 between Delcath Systems, Inc. and Rosalind Master Fund LP as signatory to the Securities Purchase Agreement dated as of April 18, 2019 and the 8% Senior Secured Promissory Note issued pursuant thereto.
8. Indebtedness of \$370,000 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$550,000 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of April 26, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
9. Indebtedness of \$550,000 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$550,000 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of May 9, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.
10. Indebtedness of \$559,500 between Delcath Systems, Inc. and Rosalind Master Fund LP and \$559,500 between Delcath Systems, Inc. and Rosalind Opportunities Fund I LP, in each case as signatories to the Securities Purchase Agreement dated as of May 23, 2019 and the 8% Senior Secured Promissory Notes issued pursuant thereto.

### **Existing Liens**

1. Liens of Silicon Valley Bank on account nos. 3301246486 and 3301264690, respectively, securing the letters of credit described in numbers 1 and 2 above.
2. Lien of Silicon Valley Bank account no. 3301464115 securing the Indebtedness described in number 3 above.
3. Lien of the institutional investor securing the Obligations described in numbers 5 - 10 above.

**SEC Reports; Financial Statements**

The Company has not timely filed its Annual Report on Form 10-K or its Proxy Statement for the year ended December 31, 2018.

The Company has not timely filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

**Material Changes; Undisclosed Events, Liabilities or Developments**

See Schedule 3.1(m).

**Litigation**

1. In March 2019, the Company sued two affiliated Iroquois Funds and FirstFire seeking declaratory judgment, among other remedies, that the February 2018 warrants issued to them are deemed to not including an “exploding” antidilution feature upon a down round financing. The suit was filed in New York State Supreme Court in NY County, NY.

See Schedule 3.1(m) below for any potential claims.

**Compliance**

UBC Demand Letter for \$2,106,116.00.

Payables to Roth Capital in the amount of \$552,642.60.

Notices of Default from Discover Growth Fund, Discover Growth Fund, LLC, Bigger Capital Fund, LP and District 2 Capital Fund LP in respect of the Indebtedness listed in paragraph 5 of Schedule 3.1(h).

Title to Assets

See Schedule 3.1(h).

**Material Agreements**

See Schedule 3.1(m).



**Intellectual Property**

None.

**Transactions with Affiliates and Employees**

Herein below are all back salaries and unreimbursed employee expenses through April 15, 2019:

Jennifer Simpson	\$	862,376
Barbra Keck	\$	536,181
John Purpura	\$	553,491
All other employees	\$	335,670
	\$	2,287,718

Cash Payments

None.

Certain Fees

None.

**Registration Rights**

Warrants issued in February 2018

September 21, 2018 Securities Purchase Agreement

Accountants

Marcum LLP

Grant Thornton LLP (with respect to 2015, 2016 and 2017 audited financials only)

Seniority

See Schedule 3.1(h).

Off-balance Sheet Arrangements

None.



**Investor Relations**

None.

**Use of Proceeds**

To redeem the Warrants listed in Schedule 1.1(a) and (b).

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO REGULATION D OR AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

**Original Issue Date: June 6, 2019**

**Original Principal Amount:**

**\$ \_\_\_\_\_**

**8% SECURED PROMISSORY NOTE  
DUE JUNE 6, 2021**

THIS 8% SECURED PROMISSORY NOTE is one of a series of duly authorized and validly issued 8% Secured Promissory Notes of Delcath Systems, Inc., a Delaware corporation (the "Company"), having its principal place of business at 1633 Broadway, Suite 22C, New York, NY 10019, designated as its 8% Secured Promissory Note due June 6, 2021, (this "Note", or collectively with the other Notes of such series, the "Notes").

FOR VALUE RECEIVED, the Company promises to pay to \_\_\_\_\_ (the "Holder"), or shall have paid pursuant to the terms hereunder, the principal sum of \$ \_\_\_\_\_ on June 6, 2021 (the "Maturity Date") or such earlier date as this Note is required or permitted to be repaid as provided hereunder, and to pay interest to the Holder on the aggregate then outstanding principal amount of this Note in accordance with the provisions hereof. This Note is subject to the following additional provisions:

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Note, (a) capitalized terms not otherwise defined herein shall have the meanings set forth in the Purchase Agreement (as defined below) and (b) the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bankruptcy Event" means any of the following events: (a) the Company or any Significant Subsidiary (as such term is defined in Rule 1-02(w) of Regulation S-X for purposes of this definition) thereof commences a case or other proceeding under any bankruptcy, reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction relating to the Company or any Significant Subsidiary thereof, (b) there is commenced against the Company or any Significant Subsidiary thereof any such case or proceeding that is not dismissed within

sixty (60) days after commencement, (c) the Company or any Significant Subsidiary thereof is adjudicated insolvent or bankrupt or any order of relief or other order approving any such case or proceeding is entered, (d) the Company or any Significant Subsidiary thereof suffers any appointment of any custodian or the like for it or any substantial part of its property that is not discharged or stayed within sixty (60) calendar days after such appointment, (e) the Company or any Significant Subsidiary thereof makes a general assignment for the benefit of creditors, (f) the Company or any Significant Subsidiary thereof calls a meeting of its creditors with a view to arranging a composition, adjustment or restructuring of its debts or (g) the Company or any Significant Subsidiary thereof, by any act or failure to act, expressly indicates its consent to, approval of or acquiescence in any of the foregoing or takes any corporate or other action for the purpose of effecting any of the foregoing.

“Change of Control Transaction” means the occurrence after the date hereof of any of (a) an acquisition after the date hereof by an individual or legal entity or “group” (as described in Rule 13d-5(b)(1) promulgated under the Exchange Act) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of in excess of thirty-three percent (33%) of the voting securities of the Company; (b) the Company merges into or consolidates with any other Person, or any Person merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than fifty percent (50%) of the aggregate voting power of the Company or the successor entity of such transaction; (c) the Company sells or transfers all or substantially all of its assets to another Person and the stockholders of the Company immediately prior to such transaction own less than fifty percent (50%) of the aggregate voting power of the acquiring entity immediately after the transaction; (d) a replacement at one time or within a one (1) year period of more than one-half (1/2) of the members of the Board of Directors which is not approved by a majority of those individuals who are members of the Board of Directors on the Original Issue Date (or by those individuals who are serving as members of the Board of Directors on any date whose nomination to the Board of Directors was approved by a majority of the members of the Board of Directors who are members on the Original Issue Date); or (e) the execution by the Company of an agreement to which the Company is a party or by which it is bound, providing for any of the events set forth in clauses (a) through (d) above.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.01 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“DTC” means the Depository Trust Company.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Event of Default” shall have the meaning set forth in Section 6(a).

“Excluded Taxes” means, in relation to a Holder, (i) any Taxes of a Holder imposed on the net capital or income of the Holder by a governmental authority as a result of the Holder (a) carrying on a trade or business or having a permanent establishment in any jurisdiction or political subdivision thereof; (b) being organized under the laws of such jurisdiction or political subdivision thereof; or (c) being or being deemed to be resident in such jurisdiction or political subdivision thereof;.

“Indemnified Taxes” means all Taxes other than Excluded Taxes.

“Mandatory Default Amount” means the payment of one hundred twenty-five percent (125%) of the outstanding principal amount of this Note and accrued and unpaid interest hereon, in addition to the payment of all other amounts, costs, expenses and liquidated damages due in respect of this Note.

“New York Courts” shall have the meaning set forth in Section 8(d).

“Note Register” shall have the meaning set forth in Section 2(b).

“Original Issue Date” means the date of the first issuance of this Note, regardless of any transfers of any Note and regardless of the number of instruments which may be issued to evidence such Note.

“Other Taxes” means all present or future stamp or documentary taxes or any other excise or property taxes, charges or similar levies arising from any payment made hereunder or from the execution, delivery or enforcement of, or otherwise with respect to, this Note.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Purchase Agreement” means that certain Note Purchase Agreement, dated the date hereof, by and among the Company, the original Holder and the other parties named therein, if any, as amended, modified or supplemented from time to time in accordance with its terms.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Senior Indebtedness” shall have the meaning set forth in Section 7.

“Subsidiary” means any subsidiary of the Company as set forth on Schedule 3.1(a) of the Purchase Agreement and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Taxes” includes all present and future income, corporation, capital gains, capital and value-added and goods and services or harmonized sales taxes and all stamp and other taxes and levies, imposts, deductions, duties, charges and withholdings whatsoever imposed by any governmental authority, together with interest thereon and penalties with respect thereto, if any, and charges, fees and other amounts made on or in respect thereof.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American; the Nasdaq Capital Market; the Nasdaq Global Market; the Nasdaq Global Select Market; the New York Stock Exchange; any level of the OTC Markets operated by OTC Markets Group, Inc. or the OTC Bulletin Board (or any successors to any of the foregoing).

## Section 2.

a) Payment of Interest in Cash. The Company shall pay interest to the Holder on the aggregate principal amount of this Note at the rate of eight percent (8%) per annum on a quarterly basis in arrears commencing second quarter 2019. Following the Closing Date, all interest payments hereunder shall be payable in cash, except as otherwise set forth herein. Accrued and unpaid interest shall be due and payable on each Conversion Date, on the Maturity Date or as otherwise set forth herein on any remaining principal balance of the Note.

b) Interest Calculations. Interest shall be calculated on the basis of a 360-day year, consisting of twelve (12) thirty (30) calendar day periods, and shall accrue daily commencing on the Original Issue Date until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due hereunder, has been made. Interest hereunder will be paid to the Person in whose name this Note is registered on the records of the Company regarding registration and transfers of this Note (the “Note Register”).

c) Late Fee. All overdue accrued and unpaid interest to be paid hereunder shall entail a late fee at an interest rate equal to the lesser of eighteen percent (18%) per annum or the maximum rate permitted by applicable law (the “Late Fees”) which shall accrue daily from the date such interest is due hereunder through and including the date of actual payment in full.

d) Voluntary Prepayment. So long as no Event of Default (as defined in Section 6(a)) hereof exists, at any time upon ten (10) days written notice to the Holder, the Company may prepay any portion of the then outstanding principal amount of this Note, any accrued and unpaid interest, and any other amounts due under this Note. If the Company exercises its right to prepay the Note, the Company shall make payment to the Holder of an amount in cash equal to the sum of the then outstanding principal amount of this Note, any accrued and unpaid interest and any other amounts due under this Note multiplied by one hundred percent (100%).

e) Mandatory Prepayment. During the term of the Note, if (in one or more transactions) the Company (i) sells any of its material assets or, subject to paragraph (ii) below, consummates an offering of equity or debt (or otherwise incurs any indebtedness), the Company shall make payment to the Holder of an amount in cash equal to 100% of the proceeds of such sale or offering (or other incurrence) to be applied by the Holder to repay the then outstanding obligations of the Company hereunder, or (ii) is a party to any Change of Control Transaction or offering of equity or debt (or otherwise incurs any indebtedness) in which the Company receives net proceeds of at least \$10,000,000, the Company shall make payment to the Holder of an amount in cash equal to the Principal Amount, any accrued but unpaid interest and any other amounts due under this Note multiplied by one hundred percent (100%).

Section 3      **[Reserved]**.

Section 4.      Registration of Transfers and Exchanges.

a) Different Denominations. This Note is exchangeable for an equal aggregate principal amount of Note of different authorized denominations, as requested by the Holder surrendering the same. No service charge will be payable for such registration of transfer or exchange.

b) Investment Representations. This Note has been issued subject to certain investment representations of the original Holder and may be transferred or exchanged only in compliance with applicable federal and state securities laws and regulations.

c) Reliance on Note Register. Prior to due presentment for transfer to the Company of this Note, the Company and any agent of the Company may treat the Person in whose name this Note is duly registered on the Note Register as the owner hereof for the purpose of receiving payment as herein provided and for all other purposes, whether or not this Note is overdue, and neither the Company nor any such agent shall be affected by notice to the contrary.

Section 5.      Taxes.

Payments Subject to Taxes. All payment by the Company hereunder shall be made free and clear of and without deduction or withholding for any and all Indemnified Taxes (including Other Taxes) paid or payable by the Holder or required to be withheld from a payment to the Holder, unless such Indemnified Taxes or Other Taxes are required by law or the administration thereof to be withheld or deducted. If the Holder is required by applicable law to deduct or pay any Indemnified Taxes (including any Other Taxes) in respect of any payment by or on account of any obligation of the Company hereunder, then (i) the sum payable by the Company shall be increased by such amount as is necessary so that after making or allowing for all required deductions and payments (including deductions and payments applicable to additional sums payable under this Section 5) the Holder receives an amount equal to the sum it would have received had no such deductions or payments been required, (ii) the Company shall make any such deductions required to be made by it under applicable law and (iii) the Company shall timely pay the full amount required to be deducted to the relevant governmental authority in accordance with applicable law.

b) Payment of Other Taxes by the Company. Without limiting the provisions of Section 5(a), the Company shall timely pay any Other Taxes to the relevant governmental authority in accordance with applicable law.

c) Indemnification by the Company. Without duplication of any gross-up by the Company pursuant to Section 5(a), the Company shall indemnify the Holder, within 10 days after written demand therefor, for the full amount of any Indemnified Taxes or Other Taxes (including Indemnified Taxes or Other Taxes imposed or asserted on or attributable to amounts payable under this Section 5) paid by the Holder and any penalties, interest and reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes or Other Taxes were correctly or legally imposed or asserted by the relevant governmental authority. A certificate as to the amount of such payment or liability delivered to the Company by the Holder shall be conclusive absent manifest error.

d) Evidence of Payment. As soon as practicable after any payment of Indemnified Taxes or Other Taxes by the Company to a governmental authority, the Company shall deliver to the Holder the original or a certified copy of a receipt issued by such governmental authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Holder.

e) If the Holder determines, in its sole discretion, that it has received a refund of Taxes or Other Taxes as to which it has been indemnified by the Company or with respect to which the Company has paid additional amounts pursuant to this Section 5, it shall pay to the Company an amount equal to such refund or reduction (but only to the extent of indemnity payments made, or additional amounts paid, by the Company under this Section 5 with respect to Taxes or Other Taxes giving rise to such refund), net of all out-of-pocket expenses of the Holder, and without interest (other than any net after-Tax interest paid by the relevant governmental authority with respect to such refund). The Company, upon the request of the Holder, agrees to repay the amount paid over to the Company (plus any penalties, interest or other charges imposed by the relevant governmental authority) to the Holder if the Holder is required to repay such refund or reduction to such governmental authority. This paragraph shall not be construed to require the Holder to make available its tax returns (or any other information relating to its taxes that it deems confidential) to the Company or any other Person, to arrange its affairs in any particular manner or to claim any available refund or reduction.

f) Survival. The provisions of this Section 5 shall survive repayment of all obligations under this Note and the termination of this Note.

Section 6. Events of Default.

a) “Event of Default” means, wherever used herein, any of the following events (whatever the reason for such event and whether such event shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body):



i. any default in the payment of (A) the principal amount of this Note or (B) accrued but unpaid interest, liquidated damages and other amounts owing to the Holder on this Note, as and when the same shall become due and payable by acceleration, which default, solely in the case of an interest payment or other default under clause (B) above, is not cured within three (3) Trading Days;

ii. the Company shall fail to observe or perform any other covenant, provision, or agreement contained in this Note which failure is not cured, if possible to cure, within the earlier to occur of (A) five (5) Trading Days after notice of such failure sent by the Holder or by any other Holder to the Company and (B) ten (10) Trading Days after the Company has become or should have become aware of such failure;

iii. a material default or material event of default (subject to any grace or cure period provided in the applicable agreement, document or instrument) shall occur (A) under any of the Transaction Documents or (B) any other material agreement, contract, lease, document or instrument to which the Company or any Subsidiary is obligated (and not covered by clause (vi) below);

iv. any representation or warranty made in this Note, any other Transaction Documents, any written statement pursuant hereto or thereto, any other agreement, contract, lease, document or instrument to which the Company or any Subsidiary is obligated (including those covered by clause (vi) below), or any other report, financial statement or certificate made or delivered to the Holder or any other Holder shall be untrue or incorrect in any material respect as of the date when made or deemed made;

v. the Company or any Significant Subsidiary (as such term is defined in Rule 1-02(w) of Regulation S-X) shall be subject to a Bankruptcy Event;

vi. the Company or any Subsidiary shall default on any of its obligations under any mortgage, credit agreement or other facility, indenture agreement, factoring agreement or other instrument under which there may be issued, or by which there may be secured or evidenced, any indebtedness for borrowed money or money due under any long term leasing or factoring arrangement that (a) involves an obligation greater than \$100,000 whether such indebtedness now exists or shall hereafter be created, and (b) results in such indebtedness becoming or being declared due and payable prior to the date on which it would otherwise become due and payable;

vii. the Common Stock shall not be eligible for listing or quotation for trading on a Trading Market and shall not be eligible to resume listing or quotation for trading thereon within five (5) Trading Days or the transfer of shares of Common Stock through the DTC is no longer available or “chilled”;

viii. the Company shall be a party to any Change of Control Transaction or shall agree to sell or dispose of all or in excess of 50% of its assets in one

transaction or a series of related transactions (whether or not such sale would constitute a Change of Control Transaction);

ix. **[Reserved];**

x. **[Reserved];**

xi. the Company or any Subsidiary shall: (A) apply for or consent to the appointment of a receiver, trustee, custodian or liquidator of it or any of its properties; (B) admit in writing its inability to pay its debts as they mature; (C) make a general assignment for the benefit of creditors; (D) be adjudicated as bankrupt or insolvent or be the subject of an order for relief under Title 11 of the United States Code or any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution or liquidation law or statute of any other jurisdiction or foreign country; or (E) file a voluntary petition in bankruptcy, or a petition or an answer seeking reorganization or an arrangement with creditors or to take advantage of any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution or liquidation law or statute, or an answer admitting the material allegations of a petition filed against it in any proceeding under any such law, or (F) take or permit to be taken any action in furtherance of or for the purpose of effecting any of the foregoing;

xii. if any order, judgment or decree shall be entered, without the application, approval or consent of the Company or any Subsidiary, by any court of competent jurisdiction, approving a petition seeking liquidation or reorganization of the Company or any Subsidiary, or appointing a receiver, trustee, custodian or liquidator of the Company or any Subsidiary, or of all or any substantial part of its assets, and such order, judgment or decree shall continue unstayed and in effect for any period of sixty (60) days;

xiii. the occurrence of any levy upon or seizure or attachment of, or any uninsured loss of or damage to, any property of the Company or any Subsidiary having an aggregate fair value or repair cost (as the case may be) in excess of \$100,000 individually or in the aggregate, and any such levy, seizure or attachment shall not be set aside, bonded or discharged within thirty (30) days after the date thereof;

xiv. any monetary judgment, writ or similar final process shall be entered or filed against the Company, any Subsidiary or any of their respective property or other assets for more than \$100,000, and such judgment, writ or similar final process shall remain unvacated, unbonded or unstayed for a period of forty-five (45) calendar days;

xv. any provision of this Note or any Transaction Document shall at any time for any reason (other than pursuant to the express terms thereof) cease to be valid and binding on or enforceable against the parties thereto, or the validity or enforceability thereof shall be contested by any party thereto, or a proceeding shall be commenced by the Company or any Subsidiary or any governmental authority having jurisdiction over any of them, seeking to establish the invalidity or unenforceability thereof, or the Company or any Subsidiary shall deny in writing that it has any liability or obligation purported to be created under any Transaction Document; or

xvi. the occurrence of any event described in Rule 506(d)(1) under the Securities Act, (2) the Company or any Subsidiary is indicted, charged with or convicted of any crime, (3) any Affiliate of the Company or any person who is an officer, director or member of senior management of the Corporation or any Subsidiary is arrested, indicted, charged with or convicted of any felony other crime involving moral turpitude, (4) the Commission, Department of Justice, Food and Drug Administration, or any similar government enforcement or regulatory agency files a complaint in any court or institutes administrative proceedings in any jurisdiction against the Corporation, any Affiliate, or any member of management.

- b) Remedies Upon Event of Default. If any Event of Default occurs, then the outstanding principal amount of this Note, plus accrued but unpaid interest, liquidated damages and other amounts owing in respect thereof through the date of acceleration, shall become, at the Holder's election, immediately due and payable in cash at the Mandatory Default Amount. After the occurrence of any Event of Default that results in the eventual acceleration of this Note, the interest rate on this Note shall accrue at an additional interest rate equal to the lesser of one and one-half percent (1.5%) per month (eighteen percent (18.0%) per annum) or the maximum rate permitted under applicable law. Upon the payment in full of the Mandatory Default Amount, the Holder shall promptly surrender this Note to or as directed by the Company. In connection with such acceleration described herein, the Holder need not provide, and the Company hereby waives, any presentment, demand, protest or other notice of any kind (other than the Holder's election to declare such acceleration), and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder and all other remedies available to it under applicable law. Such acceleration may be rescinded and annulled by Holder at any time prior to payment hereunder and the Holder shall have all rights as a holder of the Note until such time, if any, as the Holder receives full payment pursuant to this Section 6(b). No such rescission or

annulment shall affect any subsequent Event of Default or impair any right consequent thereon.

**[Section 7.        [Reserved].]**

**Section 8.        Miscellaneous.**

a)        Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company at 1633 Broadway, Suite 22C, New York, NY 10019, 917-591-5970, [bkeck@delcath.com](mailto:bkeck@delcath.com) or such other address, facsimile number, or email address as the Company may specify for such purposes by notice to the Holder delivered in accordance with this Section 8(a). Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email or facsimile, or sent by a nationally recognized overnight courier service addressed to each Holder at the email address, facsimile number, or address of the Holder appearing on the books of the Company, or if no such email address, facsimile number, or address appears on the books of the Company, at the principal place of business of such Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto prior to 12:00 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 12:00 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

b)        Absolute Obligation. Except as expressly provided herein, no provision of this Note shall alter or impair the obligation of the Company, which is absolute and unconditional, to pay the principal of, liquidated damages and accrued interest, as applicable, on this Note at the time, place, and rate, and in the coin or currency, herein prescribed. This Note is a direct debt obligation of the Company. Unless otherwise agreed by the Holder this Note ranks *pari passu* with those promissory notes hereafter issued under the terms of the Purchase Agreement.

c)        Lost or Mutilated Note. If this Note shall be mutilated, lost, stolen or destroyed, the Company shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated Note, or in lieu of or in substitution for a lost, stolen or destroyed Note, a new Note for the Principal Amount so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such Note, and of the ownership hereof, reasonably satisfactory to the Company.

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Note shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Transaction Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in the City of New York, Borough of Manhattan (the “New York Courts”). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such New York Courts, or such New York Courts are improper or inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Note and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. **EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS NOTE OR THE TRANSACTIONS CONTEMPLATED HEREBY.** If any party shall commence an action or proceeding to enforce any provisions of this Note, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys’ fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

e) Waiver. Any waiver by the Company or the Holder of a breach of any provision of this Note shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Note. The failure of the Company or the Holder to insist upon strict adherence to any term of this Note on one or more occasions shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Note on any other occasion. Any waiver by the Company or the Holder must be in writing.

f) Amendments. The prior written consent of 50.1% in interest of the Holders, which shall be calculated based on the principal amount of all Notes outstanding at the time of such consent, shall be required for any change or amendment to the Notes.

g) Severability. If any provision of this Note is invalid, illegal or unenforceable, the balance of this Note shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law. The Company covenants (to the extent that it may lawfully do so) that it shall not at any time insist upon, plead, or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension or usury law or other law which would prohibit or forgive the Company from paying all or any portion of the principal of or interest on this Note as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this Note, and the Company (to the extent it may lawfully do so) hereby expressly waives all benefits or advantage of any such law, and covenants that it will not, by resort to any such law, hinder, delay or impede the execution of any power herein granted to the Holder, but will suffer and permit the execution of every such as though no such law has been enacted.

h) Remedies, Characterizations, Other Obligations, Breaches and Injunctive Relief. The remedies provided in this Note shall be cumulative and in addition to all other remedies available under this Note and any of the other Transaction Documents at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the Holder's right to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Note. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, conversion and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Holder shall be entitled, in addition to all other available remedies, to an injunction restraining any such breach or any such threatened breach, without the necessity of showing economic loss and without any bond or other security being required. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Note.

i) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

j) Payment of Collection, Enforcement and Other Costs. If (i) this Note is placed in the hands of an attorney for collection or enforcement or is collected or enforced through any legal proceeding or the Holder otherwise takes action to collect amounts due under this Note or to enforce the provisions of this Note or (ii) there occurs any bankruptcy, reorganization, receivership of the Company or other proceedings affecting Company creditors' rights and involving a claim under this Note, then the Company shall pay the reasonable and documented out-of-pocket costs incurred by the Holder for such collection, enforcement or action or in connection with such bankruptcy, reorganization, receivership or other proceeding, including, but not limited to, attorneys' fees and disbursements.

k) Headings. The headings contained herein are for convenience only, do not constitute a part of this Note and shall not be deemed to limit or affect any of the provisions hereof.

*[Signature Pages Follow]*

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed by a duly authorized officer as of the date first above indicated.

**DELCATH SYSTEMS, INC.**

By: \_\_\_\_\_  
Name:  
Title:



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

I, Jennifer K. Simpson, certify that:

- 1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE  
June 14, 2019

/s/ Jennifer K. Simpson  
\_\_\_\_\_  
Jennifer K. Simpson  
President and Chief Executive Officer  
(Principal Executive Officer)

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

I, Barbra C. Keck, certify that:

- 1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE  
June 14, 2019

/s/ Barbra C. Keck  
\_\_\_\_\_  
Barbra C. Keck  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting  
Officer)

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

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the “Company”) for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Jennifer K. Simpson, the President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE  
June 14, 2019

/s/ Jennifer K. Simpson  
\_\_\_\_\_  
Jennifer K. Simpson  
President and Chief Executive Officer  
(Principal Executive Officer)

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

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the “Company”) for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Barbra C. Keck, the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE  
June 14, 2019

/s/ Barbra C. Keck  
\_\_\_\_\_  
Barbra C. Keck  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)