Filed pursuant to Rule 424(a)
Registration No. 333-235904

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 3, 2020

PRELIMINARY PROSPECTUS

1,470,588 Shares of Common Stock

We are offering $25,000,000 of shares of common stock in this offering.

Our common stock is quoted on the OTCQB marketplace under the symbol "DCTH." On December 24, 2019, we effected a one-for-700 reverse split of our common stock, or the Reverse Split. Unless otherwise specified or the context otherwise indicates, the information contained in this prospectus has been adjusted to give effect to the Reverse Split. On January 9, 2020, the closing sale price of our common stock as reported on the OTCQB was $17.00 per share. We have applied to list our common stock on The NASDAQ Capital Market under the symbol "DCTH." We will not consummate this offering unless our common stock is approved for listing on The NASDAQ Capital Market.

The public offering price per share will be determined between us, the underwriter and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the actual public offering price.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7.

	Per Share	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds to us (before expenses)	$	$

(1) See "Underwriting" beginning on page 82 for additional information regarding the compensation payable to the underwriter.

We have granted the underwriter a 30-day option to purchase up to an additional shares from us at the public offering price, less the underwriting discount, to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock is expected to be made through the facilities of the Depository Trust Company on or about , 2020.

Sole Book-Running Manager

Roth Capital Partners

Co-Manager

Aegis Capital Corp.

The date of this prospectus is , 2020

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Neither we nor the underwriter have authorized anyone to provide you with information other than that contained in this prospectus. We and the underwriter take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriter are offering to sell, and seeking offers to buy, the securities offered hereby only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

This prospectus includes industry data and forecasts that we have obtained from industry publications and surveys, public filings and internal company sources. Industry publications and surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of the included information. Statements as to our market position and market estimates are based on independent industry publications, government publications, third party forecasts, management's estimates and assumptions about our markets and our internal research. While we are not aware of any misstatements regarding the market, industry or similar data presented herein, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the headings "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements" in this prospectus.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It does not contain all of the information you need to consider in making your investment decision. Before making an investment decision, you should read this entire prospectus carefully and you should consider, among other things, the matters set forth under "Risk Factors" and our financial statements and related notes thereto appearing elsewhere in this prospectus. In this prospectus, except as otherwise indicated, "Delcath," "Delcath Systems," the "Company," "we," "our," and "us" refer to Delcath Systems, Inc., a Delaware corporation and its subsidiaries. "Delcath" is our registered United States trademark.

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphalan/HDS is approved for sale under the trade name Delcath Hepatic CHEMOSAT ® Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial. For information on the FOCUS Trial, see "Business—Clinical Development Program—The FOCUS Trial".

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. For information on the ALIGN Trial, see "Business—Clinical Development Program—The ALIGN Trial" below.

In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and sponsorship of select investigator-initiated trials, or IITs.

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

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Cancers in the Liver—A Significant Unmet Need

According to the American Cancer Society's, or ACS, *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 cancer that spreads to the liver is one of the leading causes of cancer death. Cancer that begins in one area of the body often metastasizes to the liver. Patient prognosis is generally poor once cancer has spread to the liver. Consequently, cancers of the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers of the liver consist of primary liver cancer and metastatic liver cancer. Primary liver cancer (hepatocellular carcinoma, or HCC, including 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 cancer, also called liver metastasis, or secondary liver cancer, results from the spread or “metastases” of a primary cancer into the liver. 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.

There are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, immunotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS 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.

Ocular Melanoma

Ocular melanoma frequently metastasizes to the liver. Based on third party research that we commissioned in 2018, we estimate that approximately 3,700-4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 50-55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients will develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is generally 3.9 months (untreated) to 6.3 months (treated). There is no one standard of care for patients with ocular melanoma liver metastases. Based on the research conducted in 2018, we estimate that approximately 1,400-2,150 patients with ocular melanoma liver metastases in the United States, the United Kingdom and the EU may be eligible for treatment with the Melphalan/HDS annually. Based on our reimbursement experience with CHEMOSAT, we estimate the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $200 million per year.

Intrahepatic Cholangiocarcinoma

Primary liver cancers include HCC and ICC. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 42,810 new cases of these cancers are expected to be diagnosed in the United States in 2020 leading to approximately 30,160 deaths.

ICC is the second most common form of primary liver cancer and according to Wang et al., 2013 J Clin Oncol 31:1188-1195 accounts for 5-30% of primary liver cancers 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, the United Kingdom and the EU annually could be candidates for treatment with Melphalan/HDS. Based on our reimbursement experience with CHEMOSAT, we estimate the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $825 million per year.

According to the ACS, the overall five-year survival rate for primary liver cancers in the United States is approximately 18%. For patients diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 33%.

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’s circulatory system. During the procedure, known as percutaneous hepatic perfusion, PHP ®, or 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 system, 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.

Recent Developments

On July 11, 2019, we entered into a securities purchase agreement with certain accredited investors pursuant to which we sold to investors an aggregate of 20,000 shares of our Series E convertible preferred stock, par value $0.01 per share, or the Series E Preferred Stock, at a price of $1,000 per share and a warrant, or a 2019 E Warrant, to purchase a number of shares of common stock, equal to the number of shares of common stock issuable upon conversion of the Series E Preferred Stock purchased by the investor, or the July 2019 Private Placement. In connection with the July 2019 Private Placement, we exchanged $11.8 million of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and related 2019 Warrants, $0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related 2019 Warrants and issued 923 shares of Series E Preferred Stock and related 2019 Warrants to certain investors in exchange for a waiver of rights under exchange agreements signed in December 2018 and March 2019, or the Debt Exchange.

On August 19, 2019, we entered into a securities purchase agreement with certain accredited investors pursuant to which we sold to investors an aggregate of 9,510 shares of Series E-1 convertible preferred stock, par value $0.01 per share, or the Series E-1 Preferred Stock, at a price of $1,000 per share and a warrant, or a 2019 E-1 Warrant, and together with the 2019 E Warrant, the 2019 Warrants, to purchase a number of shares of common stock of the Company equal to the number of shares of common stock issuable upon conversion of the Series E-1 Preferred Stock purchased by the investor, or the August 2019 Private Placement, and, collectively with the July 2019 Private Placement, the Private Placements.

Each share of Series E Preferred Stock and Series E-1 Preferred Stock, or, collectively, the Preferred Stock, was originally convertible at any time at the option of the holder into the number of shares of common stock determined by dividing the stated value by the conversion price of $42.00, subject to certain limitations and adjustments, or the Conversion Price. Except for certain adjustments, the holders of the Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an "as converted" basis) to and in the same form as dividends paid on shares of the common stock. Any such dividends that are not paid to the holders of the Preferred Stock will increase the stated value. No other dividends will be paid on shares of Preferred Stock. Each 2019 Warrant had an original exercise price equal to $42.00, subject to adjustment in accordance with the terms of the 2019 Warrants, or the Exercise Price, and became exercisable at any time upon the consummation of the Reverse Split and will be exercisable until 5:00 p.m. (NYC time) on the date that is five years following the date of the Reverse Split.

Pursuant to the terms of the Preferred Stock and the 2019 Warrants, the Conversion Price of the Preferred Stock and the Exercise Price of the 2019 Warrants were initially subject to adjustment in each of the following circumstances: (i) on the third trading day following the date that the Company effects a reverse stock split, or the Reverse Split Reset Date, (ii) the date that the initial registration statement covering the shares of common stock issuable upon the conversion of the Preferred Stock and the exercise of the 2019 Warrants is declared effective by the SEC, or the Registration Reset Date, and (iii) in the event that all of the shares of common stock which we were required to register with the SEC were not then registered on an effective registration statement, the date that all of the shares underlying the respective Preferred Stock and 2019 Warrants may be sold pursuant to Rule 144, or the Rule 144 Reset Date, each of such reset dates, a Reset Date and, collectively, the Reset Dates. On each Reset Date, the Conversion Price and the Exercise Price were to be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price or Exercise Price, as applicable, and (y) 90% of the average of the five daily volume weighted average prices of the common stock immediately prior to each Reset Date, or the Reset Formula. In the event of a reduction in the Exercise Price, the aggregate number of Warrant Shares issuable upon the exercise of the 2019 Warrants were to be increased such that the aggregate Exercise Price of the Warrants on the day immediately following such Reset Date equaled the aggregate Exercise Price immediately prior to such adjustment. In addition, from the date of issuance of the Preferred Stock and Warrants until such time that the Company's common stock is listed or quoted on a national exchange, the Conversion Price and the Exercise Price are subject to price-based anti-dilution protections.

The Registration Reset Date occurred on November 7, 2019. However, pursuant to the Reset Formula, no reduction in the Conversion Price or the Exercise Price occurred on the Registration Reset Date. The Reverse Split Reset Date occurred on December 30, 2019. Pursuant to the Reset Formula, the Conversion Price and the Exercise Price were reduced to $25.36 per share as of the Reverse Split Reset Date. The Rule 144 Reset Date with respect to the Series E Preferred Stock and the Series E Warrants will occur on January 15, 2020, and we do not expect any reset in the Conversion Price or the Exercise Price of the Series E Preferred Stock or the Series E Warrants to occur as of such date because all of the shares of common stock issuable in respect of such securities have been registered for resale. The Rule 144 Reset Date with respect to the Series E-1 Preferred Stock and the Series E-1 Warrants will occur on February 19, 2020. Based on the assumed public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020, we do not expect any reset in the Conversion Price or the Exercise Price of the Series E-1 Preferred Stock or the Series E-1 Warrants to occur as of such date because all of the shares of common stock issuable in respect of such securities have been registered for resale. However, if the public offering price is less than $16.10 per share, a reset of the Conversion Price of the Series E-1 Preferred Stock and the Exercise Price of the Series E-1 Warrants could occur which could require us to issue additional shares of common stock upon the conversion of the Series E-1 Preferred Stock and the exercise of the Series E-1 Warrants, unless the holders of such securities agree to waive their right to such reset.

On October 29, 2019, we entered into a Waiver and Forbearance Agreement , or the Waiver, with Rosalind Master Fund LP and Rosalind Opportunities Fund I LP, holders of our Series E and Series E-1 Convertible

Preferred Stock and related 2019 Warrants, or Rosalind, pursuant to which Rosalind agreed, among other things, to waive our obligation to register for resale 321,408,352 shares of common stock issuable to Rosalind (before giving effect to the Reverse Split), or the Rosalind Shares, and forbear from exercising its right to liquidated damages under the registration rights agreements entered into in connection with the Private Placements and the Debt Exchange until the earlier of (x) December 28, 2019, or the Extension Date, and (y) the date that any of the other holders of the securities issued in the Private Placements became entitled to receive liquidated damages under such registration rights agreements. Because we did not register the resale of the Rosalind Shares until January 7, 2020, we are liable to Rosalind for liquidated damages under the terms of the registration rights agreements relating to the Private Placements and the Debt Exchange for the period from December 28, 2019 and January 7, 2020.

Corporate Information

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100. Our website address is http://www.delcath.com. Information contained in our website does not constitute any part of, and is not incorporated into, this prospectus.

THE OFFERING

Common stock offered by us	1,470,588 shares of our common stock (1,691,176 shares if the underwriter exercises the over-allotment option in full), assuming a public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020.
Common stock to be outstanding after this offering	1,539,144 shares of our common stock(1) (1,759,732 shares if the underwriter exercises the over-allotment option in full)), assuming a public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020.
Use of proceeds	We intend to use the net proceeds of this offering for working capital and general corporate purposes, including the continued development of Melphalan/HDS. See “Use of Proceeds” beginning on page 33.
Risk factors	Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 7.
OTCQB Symbol	Our common stock is quoted on the OTCQB under the symbol “DCTH.”
Proposed NASDAQ listing and symbol	We have applied to list our common stock on The NASDAQ Capital Market under the symbol “DCTH.” We will not consummate this offering unless our common stock is approved for listing on The NASDAQ Capital Market.
Transfer agent and registrar	American Stock Transfer & Trust Company, LLC

(1) The table and discussion above are based on 68,556 shares of common stock outstanding as of January 9, 2020 and excludes, as of that date, the following:

- 1,634,985 shares of common stock issuable upon conversion of the outstanding Preferred Stock;
- 1,659,568 shares of common stock issuable upon the exercise of outstanding warrants having a weighted average exercise price of $25.36 per share;
- 1,640 shares of common stock issuable upon the exercise of outstanding options having a weighted average exercise price of $196.70 per share;
- 63,493 shares of common stock issuable upon the conversion of convertible notes; and
- 502 shares available for grant under our 2019 Equity Incentive Plan, or the 2019 Plan.

Except as otherwise indicated herein, all information in this prospectus has been adjusted to give effect to the Reverse Split, and assumes no exercise by the underwriter of its over-allotment option to purchase additional shares.

RISK FACTORS

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 the securities offered hereby could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Financial Condition

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 June 14, 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 our Annual Report on Form 10-K filed with the Commission on June 14, 2019, 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 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 do not include any adjustments that might result from the outcome of this uncertainty. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We received a complete response letter from the FDA 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 we 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, or 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 we must perform additional “well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS Kit using overall survival as the primary efficacy outcome measure” and which “demonstrates that the clinical benefits of Melphalan/HDS Kit outweigh its risks.” The FDA also required that the additional clinical trial(s) be conducted using the product we intend to market. Prior to conducting additional clinical trials, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information.

We have initiated a pivotal Phase 3 trial in ocular melanoma metastases. We 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 our conducting a study outside of a SPA agreement. However, we 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, we conduct and participate 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, we initiated a Phase 2 clinical trial with Melphalan/HDS for hepatocellular carcinoma, or 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, or 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.

Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT® and Melphalan/HDS and we have 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, we have no other products to sell. In addition, since CHEMOSAT currently is approved for commercialization solely in the European Union, or the EU, and limited other jurisdictions, if medac GmbH, or medac, our third-party distributor, is unsuccessful in commercializing the product in the EU and/or if Melphalan/HDS is not approved in the United States and elsewhere, we will have no means of generating revenue. In September 2013, the FDA issued a CRL with respect to our NDA for Melphalan/HDS. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude approval of the NDA in its then current form. Accordingly, we do not expect to realize any revenues from product sales in the United States in the next several years, if at all. As a result, our revenue sources are, and will remain, extremely limited unless and until our 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 September 30, 2019, we had $15.5 million in cash and cash equivalents. We have had minimal revenue to date, and have a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2018 and 2017, we incurred net losses of approximately $19.2 million and $45.1 million, respectively and expect to continue to incur losses in 2019. To date, we have funded operations through a combination of private placements and public offerings of its securities, including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, engage in product development and the regulatory approval process and commercialization of CHEMOSAT and Melphalan/HDS or any other versions of these products. If we are unable to raise capital or generate sufficient revenue, we may not be able to pay its debts when they become due and may have to seek protection under federal bankruptcy law or enter into a receivership.

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

We will require additional substantial financing to complete our clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize our product in the EU and any other markets where we may receive approval for our products. In addition, we are obligated to make payments under long-term research and development obligations and lease agreements. If financing is unavailable to make the required payments under these agreements, we could be subject to legal liability and our ability to complete product development projects or clinical trials could be impaired. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to further commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete our 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.

We are not permitted to market Melphalan/HDS in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause 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 we;
- 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 we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, we submitted the 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 we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product we intends to market. Prior to conducting additional clinical trials, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information. However, even if we complete these clinical trials and satisfy all the requirements of the CRL, we may not obtain regulatory approval from the FDA. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

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

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

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

We are limited to marketing CHEMOSAT in the EU as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EU 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, our sales opportunities in the EU will be significantly limited.

We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in any other country where we receive marketing authorization or approval.

In April 2012, we obtained the required certification from its European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Generation Two version of CHEMOSAT. In order to maintain the right to affix the CE Mark in the EU, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Generation Two 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, we will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMPs, , good clinical practices, or GCPs, , and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any pre-clinical or clinical trials that we conducts post-approval. In addition, post-marketing requirements for CHEMOSAT and Melphalan/HDS may include implementation of a risk evaluation and mitigation strategies, or 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 we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States will take many years, require substantial resources and may never lead to the approval of Melphalan/HDS by the FDA for use in the United States.

We cannot sell or market Melphalan/HDS with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for Melphalan/HDS. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agents or compounds used in our system. We are seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. We must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with the system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of Melphalan/HDS with melphalan or any other chemotherapeutic agent or compound we 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. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete the clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for Melphalan/HDS and the use of melphalan or other chemotherapeutic agents, on our business, results of operations, financial condition and prospects would be materially and adversely affected.

In August 2012, we submitted a NDA seeking an indication for ocular melanoma liver metastases for Melphalan/HDS. In September 2013, the FDA issued a CRL indicating that we must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. 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 our business, financial condition and results of operations.

Even if we obtain regulatory approval for Melphalan/HDS in the United States, our 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, we 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, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require we to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market Melphalan/HDS for other indications.

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

We have initiated an open-label Phase 3 clinical trial in ocular melanoma liver metastases called the FOCUS Trial. We also have initiated a Phase 3 registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), called the ALIGN trial.

It may take several years to complete the testing of Melphalan/HDS for use in the treatment of these indications, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;

- enrollment in our clinical trials may proceed more slowly than expected;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase 3 trial, relating to our NDA submissions;
- the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

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

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

FDA has granted us six orphan drug designations and we may seek additional orphan drug designations in the future.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We rely 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 us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for Melphalan/HDS, but rely on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on its own. We rely on third parties to conduct monitoring and data collection of our ongoing and future clinical trials, including our Phase 3 ocular melanoma trial and pivotal ICC trial. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for Melphalan/HDS if these requirements are not met.

Purchasers of CHEMOSAT in the EU may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, Our may not be able to successfully commercialize CHEMOSAT in the EU.

We have obtained the right to affix the CE Mark for CHEMOSAT, and under the definitive licensing agreement, or the medac License, for CHEMOSAT commercialization in Europe with medac, medac intends to seek third-party or government reimbursement within those countries in the EU where it expects to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic-related group code, or 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 our 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 EU 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 EU 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 EU.

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

Our 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 EU. We will seek reimbursement by third-party payors of the cost of Melphalan/HDS after its use is approved, but there are no assurances that adequate third-party coverage will be available to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for healthcare providers.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT 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, or the ACA, was enacted 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 has eliminated the individual shared responsibility penalty portion of ACA. A court decision finding that the ACA is unconstitutional is on appeal.

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 payers as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT 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.

We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and the EU.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States we are subject to various state and federal privacy and data security regulations, including but not limited to HIPAA and as amended in 2014 by the HITECH Act. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the EU, and this regulation will become more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) comes into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

Consolidation in the healthcare industry could lead to demands for price concessions.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States and foreign markets may result in a consolidation of purchasing decisions for potential healthcare provider customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of CHEMOSAT 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 EU of which we are 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, we may be unable to successfully commercialize our product in the EU.

Under the current regulatory scheme in the EU, 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 EU for over a decade, we are aware that there are currently three approved manufacturers of melphalan in certain countries of the EU. 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 our sales opportunities in the EU. Additionally, melphalan is not available in certain foreign countries outside the EU where we may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, we will be unable to commercialize CHEMOSAT in these markets, thereby limiting future sales opportunities.

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

We have entered into a manufacturing and supply agreements with several suppliers for our supply of melphalan for injection for our clinical trials. We may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents for use in the future for our clinical trial program and the commercialization of CHEMOSAT and Melphalan/HDS, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. Every manufacturer is subject to inspection by FDA and must meet all cGMP regulatory requirements. To manufacture melphalan or other chemotherapeutic agents on our own, we would have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for use with our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if it should encounter delays or difficulties in our 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, our 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.

We have implemented 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, or ISO, with respect to products sold in the EU. We are required to maintain ISO 13485 certification for medical devices to be sold in the EU, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. All of our 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 EU, and any facilities in the EU would have to obtain and maintain similar approvals or certifications of compliance.

We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS.

We do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture 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 EU 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 us in small quantities and may require significantly greater quantities to further commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from existing suppliers or need 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 we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT and Melphalan/HDS in markets outside the EU, because of inadequate infrastructure or an ineffective commercialization strategy.

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

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

Our plan to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and Melphalan/HDS may not be successful.

We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in its search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all. Our collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and Melphalan/HDS or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or

prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We will not control the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and Melphalan/HDS or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

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

Currently we have only received authorization to market CHEMOSAT in the EU, and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of CHEMOSAT to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

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

If we fail to overcome the challenges it encounters in our international operations, our 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 our 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 surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

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

The loss of key personnel could adversely affect our business.

Our success depends upon the efforts of our employees. The loss of any of our 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. 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, our 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.

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 foreign countries, to the extent we can in 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, or the 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, such as inter partes review, post-grant review, re-examination or opposition proceedings, before the USPTO, the European Patent Office or other foreign counterparts. Third parties may also 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 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 Union.

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 EU, we rely on design patent and trade secret protection for CHEMOSAT and Melphalan/HDS. Without utility patent protection in the EU 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 EU, 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 where we receive approval as mentioned in the section "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Intellectual Property and Other Rights*". 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

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

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

Risks Related to Our Common Stock

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

The trading price of our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us 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 our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading, regardless of our 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 our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;
- failure of our 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 us or our 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 us, our 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 our 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 our 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 our 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 our financial condition and results of operations.

Under certain circumstances, we may become obligated to pay liquidated damages or to issue additional shares of common stock under the terms of certain of our outstanding securities.

As described above under "Prospectus Summary – Recent Developments," we are liable to Rosalind for liquidated damages under the terms of the registration rights agreements relating to the Private Placements and the Debt Exchange for the period from December 28, 2019 and January 7, 2020. In addition, if the public offering price is less than $16.10 per share, a reset of the Conversion Price of the Series E-1 Preferred Stock and the Exercise Price of the Series E-1 Warrants could occur which could require us to issue additional shares of common stock upon the conversion of the Series E-1 Preferred Stock and the exercise of the Series E-1 Warrants, unless the holders of such securities agree to waive their right to such reset. We will also be liable for liquidated damages if we fail to comply with certain covenants contained in the registration rights agreements relating to the Private Placements and the Debt Exchange.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise additional equity capital.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could cause the market price of our common stock to decline and could impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our shares of common stock or other equity-related securities would have on the market price of our common stock.

We have a history of reverse splits, which have severely impacted our common stock price.

Since our initial public offering in 2000, we have effected five reverse stock splits, for a cumulative ratio since our IPO of 1:31,360,000,000. Each such reverse split has resulted in an effective decline in the price of our common stock. There can be no assurance that we will not be required to effect one or more additional reverse stock splits which could further impact the market price and liquidity of our common stock.

Anti-takeover provisions in our Amended and Restated Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.

Certain provisions of our Amended and Restated Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of 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, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

We intend to retain all earnings for use in connection with the expansion of our 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 our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that may be authorized and issued. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

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

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

- issue equity securities that would dilute current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel, intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our programs and even cease development and commercialization of CHEMOSAT and Melphalan/HDS;
- suffer the loss of key personnel, or

- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

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

Risks Related to this Offering

If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of your investment.

Because the public offering price per share of our common stock in this offering is expected to exceed the net tangible book value per share of our common stock, you will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Therefore, if you purchase shares of our common stock in this offering, you may pay a price per share that substantially exceeds our net tangible book value per share after this offering. Assuming the sale of 1,470,588 shares of our common stock at an assumed public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020, after deducting the underwriting discount and estimated offering expenses payable by us, you will incur immediate dilution of approximately $14.23 per share. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you participate in this offering. To the extent shares are issued under outstanding options and warrants at exercise prices lower than the public offering price of our common stock in this offering, you will incur further dilution.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may at any time offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the public offering price per share in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the public offering price per share paid by investors in this offering.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents, including the net proceeds we receive in this offering, to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline. Pending their use to fund our operations, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus 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, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. See "Risk Factors" beginning on page 7.

- 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 prospectus. 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 such applicable date or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the "Risk Factors" section hereof beginning on page 7 and in reports we will file from time to time with the Commission after the date of this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $23.0 million ($26.5 million if the underwriter exercises its over-allotment option in full), after deducting the underwriting discount and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering for working capital and general corporate purposes, including the continued development of Melphalan/HDS. We will retain broad discretion over the use of the net proceeds of this offering. Pending such use, we intend to invest the net proceeds in interest-bearing investment-grade securities or government securities.

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock is quoted on the OTCQB under the symbol “DCTH.” Quotations on the OTCQB reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. On December 24, 2019, we effected the Reverse Split. Unless otherwise specified or the context otherwise indicates, the information contained in this prospectus has been adjusted to give effect to the Reverse Split. On January 9, 2020, the closing sale price of our common stock as reported on the OTCQB was $17.00 per share.

As of January 9, 2020, there were approximately 40 holders of record of our common stock.

Dividend Policy

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2019:

- on an actual basis; and
- as adjusted to give effect to the assumed sale of 1,470,588 shares of our common stock in this offering at an assumed public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020, after deducting the underwriting discount and estimated offering expenses payable by us.

You should read the forgoing table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	As of September 30, 2019 (in thousands, except for share numbers)	
	Actual (Unaudited)	As Adjusted (Unaudited)
Stockholders' deficit:		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 42,082 shares issued and outstanding as of September 30, 2019	—	—
common stock, $0.01 par value; 1,000,000,000 shares authorized; 26,112 shares issued and outstanding as of September 30, 2019, 1,496,700 shares issued and outstanding as adjusted	—	15
Additional paid in capital	364,750	387,710
Accumulated deficit	(383,664)	(383,664)
Accumulated other comprehensive income	89	89
Total stockholders' equity (deficit)	(18,825)	4,150
Total capitalization	(18,895)	41,870

The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined between us and the underwriter at pricing.

The table and discussion above are based on 26,112 shares of common stock outstanding as of September 30, 2019 and excludes, as of that date, the following:

- 1,001,963 shares of common stock issuable upon conversion of the outstanding Preferred Stock;
- 1,002,024 shares of common stock issuable upon the exercise of outstanding warrants having a weighted average exercise price of $42.00 per share;
- 1,640 shares of common stock issuable upon the exercise of outstanding options having a weighted average exercise price of $196.70 per share;
- 63,493 shares of common stock issuable upon the conversion of convertible notes; and
- 502 shares available for grant under our 2019 Equity Incentive Plan, or the 2019 Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering.

As of September 30, 2019, we had a net tangible book deficit of approximately $(18.8 million) or approximately $(720.92) per share. Net tangible book value per share represents our total tangible assets, less total liabilities, divided by the number of shares of common stock outstanding. After giving effect to the assumed sale of 1,470,588 shares of our common stock in this offering at an assumed public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020, and after deducting the underwriting discount and estimated offering expenses payable by us, our as adjusted net tangible book value per share as of September 30, 2019, would have been approximately $4.2 million or approximately $2.77 per share. This represents an immediate increase in net tangible book value per share of $723.69 to existing stockholders and an immediate dilution of approximately $14.23 per share to new investors purchasing shares of our common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$ 17.00
Net tangible book deficit per share at September 30, 2019	$(720.92)	
Increase in book value per share attributable to new investors	723.69	
As adjusted net tangible book value per share at September 30, 2019 after this offering		$ 2.77
Dilution per share to new investors		$ 14.23

If the underwriter exercises its over-allotment option in full, our as adjusted net tangible book value would be approximately $7.6 million, or approximately $4.45 per share, representing an increase in the net tangible book value to existing stockholders of approximately $725.37 per share and immediate dilution of approximately $12.55 per share to new investors purchasing shares of our common stock in this offering.

The table and discussion above are based on 26,112 shares of common stock outstanding as of September 30, 2019 and excludes, as of that date, the following:

- 1,001,963 shares of common stock issuable upon conversion of the outstanding Preferred Stock;
- 1,002,024 shares of common stock issuable upon the exercise of outstanding warrants having a weighted average exercise price of $42.00 per share;
- 1,640 shares of common stock issuable upon the exercise of outstanding options having a weighted average exercise price of $196.70 per share;
- 63,493 shares of common stock issuable upon the conversion of convertible notes; and
- 502 shares available for grant under our 2019 Equity Incentive Plan, or the 2019 Plan.

In addition, we may choose to raise additional capital in the future. To the extent that capital is raised through equity or convertible securities, the issuance of those securities may result in further dilution to the holders of common stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus.

Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphan/HDS is approved for sale under the trade name Delcath Hepatic CHEMOSAT ® Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial. For information on the FOCUS Trial, see "Business—Clinical Development Program—The FOCUS Trial".

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. For information on the ALIGN Trial, see "Business—Clinical Development Program—The ALIGN Trial" below.

In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and sponsorship of select investigator-initiated trials, or IITs.

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

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Our Ability to Continue as a Going Concern

The notes to our financial statements include a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our

consolidated financial statements 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.

Our independent registered public accounting firm has issued its report dated June 14, 2019 (except for the reverse stock split described in Note 2 and Note 15, as to which the date is December 30, 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.

Future Capital Needs; Additional Future Funding

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve consistent profitability. Based upon recent financing activities described above, we believe that we have 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 three and nine months ended September 30, 2019; Comparisons of Results of Operations for three and nine months ended September 30, 2018

Three months ended September 30, 2019 and September 30, 2018

Revenue

We recorded approximately $0.2 million in revenue related to product sales for the three months ended September 30, 2019 and $0.8 million in revenue related to product sales for the three months ended September 30, 2018. The decrease was slightly offset by $0.2 million in other revenue. Other revenue and the decrease in product revenue are both related to our entering into the licensing agreement with medac.

Cost of Goods Sold

For the three months ended September 30, 2019, we recorded cost of goods sold of approximately $0.2 million compared to $0.2 million for the three months ended September 30, 2018. The decrease of approximately $60,000 is related to an adjustment in the allocation of expenses into COGS during 2019.

Selling, General and Administrative Expenses

For the three months ended September 30, 2019 and 2018, selling, general and administrative expenses were $4.0 million and $2.3 million, respectively. The increase for the three months ended September 30, 2019 is primarily related to $0.9 million in settlement expenses, which was a non-cash expense discussed further in Note 9 and $0.6 million in expenses related to litigation that was settled in July and August 2019.

Research and Development Expenses

For the three months ended September 30, 2019 and 2018, research and development expenses decreased to $1.8 million from $4.1 million. The decrease was primarily due to a reduced rate of enrollment and related professional services related to the ongoing accrual of our FOCUS trial. The reduction is related to the cash constraints we experienced during the first half of 2019.

Change in the fair value of the warrant liability

For the three months ended September 30, 2019 the change in the fair value of the warrant liability was approximately $0.4 million as compared to $1.2 million for the three months ended September 30, 2018. The decrease of $0.8 million is due to the reclassification of certain warrants from liability to equity in 2018 and the mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 10 to our interim condensed consolidated financial statements.

Other Income/Expense

Other expense and interest expense are primarily related to the amortization of debt discounts discussed in Note 8 of our condensed consolidated financial statements, as well as foreign currency exchange gains and losses.

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

Net Loss

We recorded a net loss for the three months ended September 30, 2019 of $7.5 million, a decrease of $1.4 million, or 15.3%, compared to net loss of $8.9 million for the same period in 2018. This increase in net loss is primarily due to a $0.6 million decrease in operating expenses, a $0.4 million decrease in gross profit, and a $1.2 million change in non-cash expense items including the fair value of the warrant liability, loss on the issuance of financial instruments and interest expense.

Nine months ended September 30, 2019 and September 30, 2018

Revenue

We recorded approximately $0.5 million in revenue related to product sales for the nine months ended September 30, 2019 and $2.4 million in revenue related to product sales for the nine months ended September 30, 2018. The decrease was slightly offset by $0.5 million in other revenue. Other revenue and the decrease in product revenue are both related to the entry into the medac License.

Cost of Goods Sold

For the nine months ended September 30, 2019, we recorded cost of goods sold of approximately $0.4 million compared to $0.6 million for the nine months ended September 30, 2018. The decrease is related to an adjustment in the allocation of expenses into COGS during 2019.

Selling, General and Administrative Expenses

For the nine months ended September 30, 2019 and 2018, selling, general and administrative expenses were $9.2 million and $7.3 million, respectively. The increase for the nine months ended September 30, 2019 is primarily related to $0.9 million in settlement expenses, which was a non-cash expense discussed further in Note 9 and $0.8 million in expenses related to litigation that was settled in July and August 2019.

Research and Development Expenses

For the nine months ended September 30, 2019 and 2018, research and development expenses decreased to $6.8 million from $13.9 million. The decrease was primarily due a reduced rate of enrollment and related professional services related to the ongoing accrual of our FOCUS trial. The reduction is related to the cash constraints we experienced during the first half of 2019.

Change in the fair value of the warrant liability

For the nine months ended September 30, 2019 the change in the fair value of the warrant liability was approximately $10,000 as compared to $18.4 million for the nine months ended September 30, 2018. The decrease of $18.0 million is due to the reclassification of certain warrants from liability to equity in 2018 and the continued mark-to-market adjustments to the remaining Warrant liability as discussed in more detail in Note 10 to our interim condensed consolidated financial statements.

Other Income/Expense

Other expense and interest expense are primarily related to the amortization of debt discounts discussed in Note 8 of our condensed consolidated financial statements, as well as foreign currency exchange gains and losses.

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

Net Loss

We recorded a net loss for the nine months ended September 30, 2019 of $21.4 million, a decrease of $13.0 million compared to net loss of $8.4 million for the same period in 2018. This increase in net loss is primarily due to a $18.0 million change in the fair value of the warrant liability, a non-cash item, a $5.2 million decrease in operating expenses and a $1.2 decrease in gross profits.

Liquidity and Capital Resources

We received gross proceeds of $29.5 million through two private placements in July and August 2019, providing funding through the second quarter of 2020. We will need to raise additional capital under structures available to us including debt and/or equity offerings. If these sources do not provide the capital necessary to fund our operations, we will need to curtail certain aspects of our operations or consider other means of obtaining additional financing, although there is no guarantee that we could obtain the financing necessary to continue our operations.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and anticipate that losses will continue over the coming years. There can be no assurance that we

will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our clinical and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and 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 September 30, 2019, we had cash, cash equivalents and restricted cash totaling $15.5 million, as compared to cash, cash equivalents and restricted cash totaling $3.6 million at December 31, 2018 and $10.0 million at September 30, 2018. During the nine months ended September 30, 2019 and 2018, we used $18.3 million and $12.9 million respectively, of cash in our operating activities.

Our condensed consolidated financial statements as of September 30, 2019 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 our business does not generate positive cash flow from operating activities, we will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to ocular melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. We believe we will be able to raise additional capital in the event it is in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our 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.

We have funded our operations through a combination of private placements and public offerings of its securities in each of 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016, 2018 and 2019, including registered direct offerings in 2007, 2009 and 2013, “at the market” equity offering programs in 2012 and 2013, and by the private placement of convertible notes in 2016 and 2018, and, most recently, in July and August 2019, we raised $29.5 million in the closing of two private placements of convertible preferred stock and warrants to purchase common stock. For a detailed discussion of our various sales of debt and equity securities see Notes 8, 9, and 14 to our condensed consolidated financial statements as well as Notes 10 and 11 to our audited consolidated financial statements.

In October 2018, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allowed us 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. We lost our Form S-3 eligibility due to the late filing of our Annual Report for the year ended December 31, 2018.

Results of Operations for the Year Ended December 31, 2018; Comparisons of Results of the Years Ended December 31, 2018 and 2017

Revenue

We recorded approximately $3.4 million in product revenue during the year ended December 31, 2018. During the same period in 2017, We 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 we continued 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, we recorded approximately $29,000 in other revenue which is related to the amortization of certain payments pursuant to the medac License.

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, we 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 our 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.

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 our audited consolidated financial statements and the amortization of debt discounts discussed in Note 10 of our audited consolidated financial statements.

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 our audited consolidated financial statements

Net Loss

We 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 our consolidated financial statements, offset by a $9.3 million increase in operating expenses primarily related to increased investment in clinical trial initiatives.

Income Taxes

We have 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, or the Tax Act, was enacted containing several key tax provisions that affected us, 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. We were 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 SEC issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, or SAB 118, which allowed us 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, we 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 we were 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 our audited consolidated financial statements. We finalized our accounting of the effects of tax reform in 2018, which resulted in insignificant adjustments.

Application of Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or 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 our audited consolidated financial statements.

We consider the valuation allowance for the deferred tax assets to be a significant accounting estimate. A valuation allowance has been recorded against our 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 we will realize the benefits of its deferred tax assets, management considers all forms of available evidence, including our history of cumulative losses, estimates of future taxable income and losses (including reversals of deferred tax liabilities), and available tax planning strategies. Since we are in a cumulative loss position, we cannot rely on future taxable income as a source of taxable income because we view a cumulative loss position as significant objective negative evidence that would be difficult to overcome with the other subjective tests discussed. We do not have taxable income in prior years to absorb the carryback of net operating losses, nor have we 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, we sold a portion of our intellectual property to an 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. We adopted ASU 2016-16, effective on January 1, 2018. As a result of adoption, we immediately recognized the $2.0 million deferred gain and none remains as of December 31, 2018.

We have adopted the provisions of Accounting Standard Codification, or 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). We expense our share-based compensation under the accelerated method, which treats each vesting tranche as if it were an individual grant.

We have 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.

We have 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 we 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. Our 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 our audited consolidated financial statements for assets and liabilities we has evaluated under ASC 820.

BUSINESS

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphan/HDS is approved for sale under the trade name Delcath Hepatic CHEMOSAT ® Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial. For information on the FOCUS Trial, see “Clinical Development Program—The FOCUS Trial” below.

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. For information on the ALIGN Trial, see “Clinical Development Program—The ALIGN Trial” below.

In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and sponsorship of select investigator-initiated trials, or IITs.

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

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Cancers in the Liver—A Significant Unmet Need

According to the American Cancer Society’s, or ACS, *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 cancer that spreads to the liver is one of the leading causes of cancer death. Cancer that begins in one area of the body often metastasizes to the liver. Patient prognosis is generally poor once cancer has spread to the liver. Consequently, cancers of the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers of the liver consist of primary liver cancer and metastatic liver cancer. Primary liver cancer (hepatocellular carcinoma, or HCC, including 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 cancer, also called liver metastasis, or secondary liver cancer, results from the spread or "metastases" of a primary cancer into the liver. 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.

There are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, immunotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS 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.

Ocular Melanoma

Ocular melanoma frequently metastasizes to the liver. Based on third party research that we commissioned in 2018, we estimate that approximately 3,700-4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 50-55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients will develop liver involvement. According to Lane et al., *JAMA Ophthalmol.* 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is generally 3.9 months (untreated) to 6.3 months (treated). There is no one standard of care for patients with ocular melanoma liver metastases. Based on the research conducted in 2018, we estimate that approximately 1,400-2,150 patients with ocular melanoma liver metastases in the United States, the United Kingdom and the EU may be eligible for treatment with the Melphalan/HDS. Based on our reimbursement experience with CHEMOSAT, we estimate the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $200 million per year.

Intrahepatic Cholangiocarcinoma

Primary liver cancers include HCC and ICC. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 42,810 new cases of these cancers are expected to be diagnosed in the United States in 2020 leading to approximately 30,160 deaths.

ICC is the second most common form of primary liver cancer and according to Wang et al., 2013 J Clin Oncol 31:1188-1195, accounts for 5-30% of primary liver cancers 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, the United Kingdom and the EU annually could be candidates for treatment with Melphalan/HDS. Based on our reimbursement experience with CHEMOSAT, we estimate the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $825 million per year.

According to the ACS, the overall five-year survival rate for primary liver cancers in the United States is approximately 18%. For patients diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 33%.

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's circulatory system. During the procedure, known as percutaneous hepatic perfusion, PHP ®, or 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 system, 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.

Early development of Melphalan/HDS System—FDA Complete Response Letter

Based on clinical trials conducted using an earlier version of our Melphalan/HDS system, in August 2012 we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, seeking FDA approval for use of our Melphalan/HDS system 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 application to ocular melanoma metastatic to the liver with an earlier version.

In the Spring of 2013, an Oncologic Drug Advisory Committee, or 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, or low blood pressure, during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression.

In September 2013, the FDA issued a complete response letter, or 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 in the CRL included, a statement that we had to 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 required that the additional clinical trial(s) be conducted using the product we intended to market, and that certain clinical, clinical pharmacology, human factors and product quality elements be addressed.

In January 2016, we entered into a Special Protocol Assessment agreement, or 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. In the summer of 2018, we amended the protocol for the trial which, after much discussion regarding improvement of the enrollment rate with FDA, resulted in the trial protocol design becoming a non-randomized, single-arm study with a different primary endpoint, which effectively terminated the SPA.

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.

Procedure and Product Refinements

In 2012, we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other device component product enhancements. Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS have indicated that these product improvements and procedure refinements have improved the safety profile of our product. Since 2017, physicians in Europe and the United States have presented and published the results of research that indicated an improved safety profile by decreasing the percentage of adverse events experienced by treated patients, as well as efficacy in multiple tumor types. Collection of adequate safety data on all aspects of the procedure is a major focus of our clinical trials.

Clinical Development Program

The focus of our clinical development program is to generate clinical data for CHEMOSAT and Melphalan/HDS in various disease states to demonstrate efficacy 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 adverse event profile and procedure-related risks that led to the issuance of the CRL. Our 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

In July 2018, we commenced an amended clinical trial of Melphalan/HDS, titled *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*, or the FOCUS Trial. Under the revised study protocol, the FOCUS Trial will study a minimum of 80 patients with ocular melanoma metastatic to the liver. The primary endpoint of the FOCUS Trial is objective response rate, or ORR as measured by RECISTv1.1. Secondary endpoints 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. Patients previously enrolled in the Melphalan/HDS arm of the original trial will continue to be treated and statistically evaluated as part of the revised FOCUS Trial. The FOCUS Trial is being conducted at approximately 30 sites in the United States and Europe.

The rarity of ocular melanoma, absence of crossover to the experimental trial arm, and the commercial availability of PHP® Therapy in Europe impeded enrollment in this trial under the original protocol. While the revised protocol of the FOCUS Trial was intended to accelerate the completion of patient enrollment, enrollment of patients in this trial was adversely affected by a lack of capital to fund the trial. Enrollment of the required patients has been completed and we expect to announce top-line data from this trial in mid-2020. Because of a lack of effective treatments for patients with unresectable hepatic-dominant ocular melanoma, we will continue to enroll eligible patients in the trial until such time as we determine the feasibility of an expanded access program and subsequent commercial availability. We anticipate filing the NDA in the first quarter of 2021.

The ALIGN Trial

In April 2018 we initiated a pivotal trial of Melphalan/HDS in 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, or the ALIGN Trial. The ALIGN Trial is being conducted under an SPA with the FDA. The ALIGN Trial will study approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint of the ALIGN Trial is overall survival, or OS, and secondary and exploratory endpoints include safety, progression-free survival, or PFS, ORR and quality-of-life measures. Under the terms of the SPA agreement for the ALIGN Trial, the pivotal trial design adequately addresses objectives that, if met, would support FDA 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.

Although, the first patient was enrolled in the ALIGN Trial in October 2018, we have experienced difficulties enrolling trial subjects under the existing trial protocol because patients that have received standard of care treatment outside of the trial are excluded. We intend to seek FDA approval to amend the trial protocol so that such patients are no longer excluded.

Prior Phase 2 Trials

In 2014 we initiated a Phase 2 clinical trial program in Europe and the United States of 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 so that we could focus our resources on our ocular melanoma study and is no longer enrolling patients.

Protocol 202 NCT02415036—Conducted in Europe, this trial was intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial was also designed to evaluate overall response rate via mRECIST criteria, progression free survival and to characterize the systemic exposure of melphalan and assess patient quality of life. This trial was terminated earlier than planned so that we could focus our resources on our ocular melanoma study and is no longer enrolling patients.

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. Enrollment of this cohort was completed in 2017; however, analysis of the data has only recently begun due to resource constraints. We expect the results of this trial to be announced before the end of 2020.

ICC Retrospective Data Collection—We did not proceed with the Phase 2 ICC trial because efficacy data for this indication was obtained from multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These outcomes and observations were discussed with Key Opinion Leaders at a Delcath-organized medical advisory panel meeting and led to the conclusion that PHP therapy does “demonstrate an efficacy signal in ICC and is worthy of full clinical investigation.” Data from the retrospective data collection were published in 2018 in “European Radiology” in a paper titled “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”.

European Clinical Data Generation

In April 2015, we created a prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry is intended to gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. Registry data is considered to be supportive data and, as such, cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable supportive data repository

that contains real-world evidence, from a commercial setting, that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

In addition, we also provide support for a number of IITs.

Recent Data Presentations

In July 2019 results from a single-institution retrospective study conducted by University Hospital of Tubingen in Germany on the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with metastatic ocular melanoma with liver metastases were published in the journal *Cancer Imaging*.

The study, *Chemosaturation with percutaneous hepatic perfusion of melphalan for liver dominant metastatic uveal melanoma: a single center experience*, by Dr. Christoph Artzner, et al, evaluated the safety and efficacy of PHP® therapy in 16 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between June 2015 and December 2018. Tumor response was evaluated following each PHP treatment using Response Evaluation Criteria in Solid Tumors, and serious adverse events, or SAEs, were evaluated using Common Criteria for Adverse Events.

The 16 patients underwent a total of 28 PHP treatments. Results of the study in the 15 evaluable patients showed that after the first PHP treatment, nine patients (60%) had a partial response, or PR, five patients (33%) had stable disease, and one patient (7%) had progressive disease for an initial disease control rate of 93%. Median PFS after the first treatment was 11.1 months. Six patients received a second PHP treatment, three patients received three treatments, and a single patient received six treatments. Median overall survival, or OS, was 27.4 months.

Safety analysis showed that grade three SAEs were observed in 14% of treatments, consisting of anemia, leukopenia and thrombocytopenia. The sole grade four SAE observed was in one patient who suffered a cardiac arrest during the first PHP treatment and was removed from the study. Subsequent evaluation determined that this patient had coronary artery occlusion which was successfully treated. Retrospective evaluation of this patient's pre-procedure imaging revealed signs of coronary artery disease, and investigators subsequently modified their screening procedures for cardiovascular risk factors. Investigators stated that most SAEs were grade one or two and that 5% of the reported grade three and four SAEs required additional intervention.

Investigators concluded that for patients with liver-dominant metastatic uveal melanoma, treatment with PHP Therapy had "observed rates for OS and PFS that exceeded the reported outcomes for traditional systemic treatment." Investigators stated that SAEs were frequent, but most did not require additional intervention, and that care should be taken in patients with suspected coronary heart disease.

In April 2019 results from a prospective Phase 2 study conducted by Leiden University Medical Center, or 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 titled "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 SAEs were recorded. The hematologic toxicities were in a majority of the cases self-limiting and manageable. The 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.”

Market Access and Commercial Clinical Adoption

Europe

Our European marketing activities include establishing strategic alliances with partners that include license, supply, sales and marketing arrangements. In December 2018, we entered into a License Agreement, or License, with medac GmbH, or medac, for the commercialization of CHEMOSAT in Europe. Under the terms of the medac License, medac has the exclusive right to sell and market CHEMOSAT in all member states of the EU, Norway, Liechtenstein, Switzerland, and the United Kingdom. Under the medac License, we are entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

Since launching CHEMOSAT in Europe, over 750 commercial treatments have been performed at over 25 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.

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, or 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.

Under the terms of the medac License, medac is required to provide support for reimbursement applications in the European markets covered by our agreement. CHEMOSAT is approved for reimbursement in the United Kingdom and Germany.

Government Regulation

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

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

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

Clinical Trials

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

- Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

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

Prior to initiating our currently ongoing Phase 3 clinical trial(s), we submitted a proposal for the design, execution and analysis under a SPA.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter, or CRL, if

the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the 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. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

Orphan Drug Exclusivity

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

We have received six orphan drug designations: two for melphalan for the treatment of patients with cutaneous melanoma, as well as patients with ocular melanoma; one for melphalan for the treatment of patients with neuroendocrine tumors; one for doxorubicin for the treatment of patients with primary liver cancer; one for melphalan for the treatment of HCC; and one for melphalan for the treatment of cholangiocarcinoma, which includes ICC.

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

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event

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

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

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

European Regulatory Environment

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

with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system.

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

We continue to evaluate commercial opportunities in select markets when resources are available and at an appropriate time.

Intellectual Property

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. We hold rights in eight U.S. utility patents, one U.S. design patent, five pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validation of a European

patent directed to our filter apparatus in eight European countries, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications. In July 2017, a patent directed to our chemotherapy filtration system was issued by the U.S. Patent and Trademark Office. 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, we actively pursue protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT 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. We intend 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 us six 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, we believe that this exclusivity 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 us, we 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, we plan to enforce our 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.

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 competes and, if approved by the FDA Melphalan/HDS will 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 local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Boston Scientific Corporation, the Covidien Products division of Medtronic plc, Merit Medical Systems, Inc., Celenova BioSciences Inc., Sirtex Medical Limited, AngioDynamics, Inc., 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 plc), 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 plc) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb Company) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech, Inc.) 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 critical medical device components including our proprietary filter media and assemble and package the CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we conduct final manufacturing, processing and assembly. We use third-parties to manufacture some components of the CHEMOSAT and Melphalan/HDS. The CHEMOSAT and Melphalan/HDS and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and we use third-party vendors to perform the sterilization process.

We are required to comply with the FDA's cGMP regulations and international quality system regulations including those established by the International Standards Organization (ISO) with respect to products sold in the

EU. We are required to maintain ISO 13485 certification for medical devices to be sold in the EU, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. Our facilities are ISO 13485:2016 certified.

Employees

As of January 3, 2020, we had approximately 30 full time employees located in the United States and in Europe. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Properties

Our corporate offices currently occupy 6,877 square feet of office space at 1633 Broadway, Suite 22C, New York, New York under a sub-lease agreement that expires in February 2021. We lease additional space in the United States comprised of approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York under a lease that expires in November 2020. We also own 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. We own approximately four acres of land at 12 and 14 Park Road in Queensbury, New York. In addition, we lease a facility for office and manufacturing comprised of approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease that expires in August 2021. We have sublet a portion of this facility to an unaffiliated third-party. We believe that our facilities are adequate for our operations.

Legal Proceedings

From time to time, we are engaged in various legal actions, claims and proceedings arising in the ordinary course of business, none of which are expected to be material.

MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

Below are the names and certain information regarding the Company's executive officers and directors:

Name	Age	Position Held
Jennifer K. Simpson, Ph.D.	51	Director, President and Chief Executive Officer
Barbra C. Keck	42	Chief Financial Officer and Secretary
John Purpura	58	Executive Vice President, Global Head of Operations
William D. Rueckert	66	Director
Roger G. Stoll, Ph.D.	76	Director, Chairman
John R. Sylvester	55	Director
Marco Taglietti, M.D.	60	Director

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.

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 the Company in December 2008. He became 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 of directors of 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 Tecnicon Company and globally integrating the Bayer and Techincon business units. This resulted in a global diagnostic business in excess of $1 billion 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.

John R. Sylvester was appointed as a Director in July 2019. He is currently serving as Chief Commercial Officer of BTG plc, which he joined in 2011 and has had roles leading both their Interventional Oncology and

Interventional Vascular businesses as well as a period as Chief Development Officer accountable for Strategy, M&A and Market access. This culminated in an exit to Boston Scientific for $4.2 billion. Prior to BTG, John was Managing Director of Biocompatibles plc, building their Interventional Oncology business which led to a successful exit to BTG for £166.0 million. John joined Biocompatibles following a period as the Vice President of Marketing for Baxter Healthcare's $750.0 million European Medication Delivery business based in Brussels then Zurich accountable for six strategic business units incorporating drugs, devices and drug device combinations. Before this, John held a number of senior commercial roles in the industrial sector. Immediately prior to Baxter Healthcare, John was the General Manager of a Minerals company with $4.0 billion of assets on three continents, $500.0 million of sales and 1,500 employees. John graduated with joint honors in Biochemistry and Applied Molecular Biology from the University of Manchester Institute of Science and Technology (U.M.I.S.T.)

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.

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, or 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, or 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 2018 and 2019:

Executive	Hire Date	2017 Base Salary	Percent Increase in 2018	2018 Base Salary	Percent Increase in 2019	2019 Base Salary
Jennifer K. Simpson, Ph.D.	3/23/2012	$453,004	3.0%	$466,594	0%	$466,594
Barbra C. Keck, M.B.A.	1/5/2009	$300,000	8.0%	$324,000	0%	$324,000
John Purpura, M.S.	11/16/2009	$316,210	5.9%	$335,000	0%	$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 is entitled. No annual bonus has been awarded or paid to any named executive officer for 2019.

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

* The annual bonus for 2019 is not calculable as of the filing date. The Company expects the annual bonus for 2019 will be calculable by March 15, 2020.

For 2019, AIP goals were based entirely on Company performance to focus all the executives on the same critical challenges facing the Company. Company performance in 2019 will be measured based upon achievement of objectives in the following areas: (1) Clinical Trials and (2) Capital. The Board is reviewing the Company's performance for 2019 and no decisions have been made at this time.

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.

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 2019, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2019. 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 ($)
Jennifer K. Simpson, Ph.D.	2019	$466,594	$106,341	$ —	$90,706	$ —	$ —	$663,641
President and Chief Executive Officer	2018	466,594	75,000	—	—	—	—	541,594
Barbra C. Keck, M.B.A.	2019	324,000	52,519	—	64,790	—	—	441,309
Chief Financial Officer and Secretary	2018	324,000	50,000	—	—	—	—	374,000
John Purpura, M.S.	2019	335,000	17,718	—	64,790	—	—	417,508
Executive Vice President, Global Head of Operations	2018	335,000	50,000	—	—	—	—	385,000

(1) For 2019, Dr. Simpson was paid $393,703, Ms. Keck was paid $274,875 and Mr. Purpura was paid $284,042. 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 2018, all bonus amounts have been accrued and not yet paid. For 2019, each NEO was awarded a bonus related to the Private Placements. The annual bonus for 2019 is not calculable as of the filing date. The Company expects the annual bonus for 2019 will be calculable by March 15, 2020.

(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 2018 which in no way should create any negative inference concerning the Compensation Committee's evaluation of their performance.

Grants of Plan-Based Awards—2019

The following table sets forth grants of plan-based awards made during the fiscal year ended December 31, 2019 to the named executive officers. All equity grants were made pursuant to the Company's 2019 Equity Incentive Plan, or the 2019 Plan. Under the 2019 Plan, 2,142 shares of common stock of the Company are available for grants through February 1, 2029 to the Company's employees, directors and consultants. 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.

Name	Grant Date	All Other Option Awards; Number of Securities Underlying Options	Exercise or Base Price of Option Awards	Grant Date Fair Value of Option Awards
Jennifer K. Simpson, Ph.D.	2/1/2019	500	$ 196.70	$ 90,706
Barbra C. Keck, M.B.A.	2/1/2019	357	$ 196.70	$ 64,790
John Purpura, M.S.	2/1/2019	357	$ 196.70	$ 64,790

Outstanding Equity Awards at Fiscal Year-End Table—2019.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2019.

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.	458	42	$196.70	2/1/2029	42	$ —
Barbra C. Keck, M.B.A.	327	30	$196.70	2/1/2029	30	$ —
John Purpura, M.S.	327	30	$196.70	2/1/2029	30	$ —

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, 2019, the last business day of 2019. Unvested, unexercised stock options and unvested restricted stock awards are valued at the closing market price of our 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 our 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.	—	—	$ 730,661	$730,661	—
Barbra C. Keck, M.B.A.	—	—	$ 536,029	$536,029	—
John Purpura, M.S.	—	—	$ 520,733	$520,733	—

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—2019

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.

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 2019.

Name	Fees Earned or Paid in Cash(2)	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation ($)	All Other Compensation	Total
Simon Pedder, Ph.D.(1)	$ 14,000	$ —	$ —	$ —	$ —	$ 14,000
William D. Rueckert	72,000	—	25,916	—	—	97,916
Roger G. Stoll, Ph.D.	87,750	—	25,916	—	—	113,666
John Sylvester	21,161	—	—	—	—	21,161
Marco Taglietti, M.D.	65,000	—	25,916	—	—	90,916

(1) Dr. Pedder resigned as a director effective April 10, 2019. John R. Sylvester was appointed director effective July 24, 2019 to fill the vacancy created.

(2) No non-employee director was paid his 2018 fees. Certain amounts were invested by directors in the July 2019 Private Placement. Mr. Rueckert and Dr. Taglietti have not been paid their 2019 fees. Their fees have been accrued.

Corporate Governance

Board of Directors. We have currently have five 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 four of our five directors (each of Roger G. Stoll, William D. Rueckert, John R. Sylvester and Marco Taglietti) are “independent” directors within the meaning of the NASDAQ listing rules.

Attendance. The Board of Directors met 19 times in 2019 (including regularly scheduled and special meetings). During 2019, 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 our company because it allows our President and CEO to concentrate on our 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 our company. For a company like ours 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 our company, 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 value of our company. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in our 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 our 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. Mr. Sylvester joined the board in July 2019 and has not been appointed to any committee yet.

Audit Committee. The Audit Committee provides assistance to the Board in fulfilling its oversight responsibilities with respect to our financial statements, our system of internal accounting and financial controls and the independent audit of our 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 Commission.

The current members of the Audit Committee are William D. Rueckert (Chair), John Sylvester and Roger G. Stoll. The Board has determined that each of William D. Rueckert and Roger G. Stoll qualifies as an "audit committee financial expert" as defined by SEC rules. During 2019, the Audit Committee met four 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, click on "Investors," then "Corporate Governance."

Compensation and Stock Option Committee. The Compensation and Stock Option Committee, or the Compensation Committee, assists the Board of Directors in the discharge of the Board's responsibilities with respect to the compensation of our 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 our 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 McCarter & English, outside legal counsel to the Compensation Committee and the Company 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 G. Stoll, each of whom is "independent" within the meaning of NASDAQ listing rules. During 2019, 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, click on "Investors," then "Corporate Governance."

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee, or 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 G. Stoll (Chairman), William D. Rueckert and Marco Taglietti, each of whom is "independent," within the meaning of NASDAQ listing rules. During 2019, the Nominating Committee met two times. The Nominating Committee has a written charter, which is available on our website; go to 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 we operate, 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 our company and our 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 our 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 us with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in our 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.

Compensation Committee Interlocks and Insider Participation. During 2019, Marco Taglietti, Roger G. Stoll and William D. Rueckert served as members of our Compensation and Stock Option Committee. None of the current members or members serving during 2019 of the Compensation and Stock Option Committee is a current or former officer or employee of our company at the time of their service on the Compensation and Stock Option Committee, nor did any Compensation and Stock Option Committee member engage in any "related person" transaction that would be required to be disclosed under Item 404 of Regulation S-K. During 2019, none of our executive officers served on the compensation committee (or equivalent) or on the board of directors of another

entity whose executive officers served on the Compensation and Stock Option Committee or our Board of Directors.

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 our employees, with regard to their company-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.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Based solely upon information made available to us, the following table sets forth information regarding the beneficial ownership of our common stock, Series E Preferred Stock and Series E-1 Preferred Stock as of January 9, 2020, held by: (i) each director and director nominees; (ii) each of the named executive officers; (iii) all of our directors and executive officers as a group; and (iv) each additional person or group who is known by us to own beneficially more than 5% of our common stock or Series E and Series E-1 Preferred Stock. 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.

	Shares Beneficially Owned[1]					
Name of Beneficial Owner:	Common Stock	Percent	Series E Convertible Preferred Stock	Percent	Series E-1 Convertible Preferred Stock	Percent
Named Executive Officers and Directors:						
Jennifer K. Simpson, Ph.D.	6,308[2]	9.2%	147[3]	*	—	—
Barbra C. Keck, M.B.A.	3,052[4]	4.3%	68[5]	*	—	—
John Purpura, M.S.	2,929[6]	4.1%	65[7]	*	—	—
Roger G. Stoll, Ph.D.	3,820[8]	5.3%	93[9]	*	—	—
William D. Rueckert	2,523[10]	3.6%	60[11]	*	—	—
Marco Taglietti, M.D.	2,510[12]	3.5%	60[13]	*	—	—
John Sylvester	—	*	—	*	—	—
All directors and executive officers as a group (7 people)[8]:	**21,142[14]**	**29.9%**	**493[15]**	**1.5%**	—	—
5% Stockholders						
Altium Capital Management, LP Altium Growth Fund, LP Altium Growth GP, LLC 551 Fifth Ave, FL 19 New York, NY 10176	6,787	9.9%	2,300[16]	7.2%	1,100	11.7%
Rosalind Master Fund L.P. Rosalind Opportunities Fund I L.P. 77 Bloor St W, 3rd FL Toronto, Ontario M5S 1M2	6,787	9.9%	16,800[17]	52.4%	2,875	30.6%
Hudson Bay Master Fund Ltd[18] 777 Third Ave, 30th Floor New York, NY 10017	6,787	9.9%	2,187[18]	6.8%	—	—

* Less than 1%

(1) (i) except as otherwise indicated in these footnotes, each stockholder named in the table above possesses sole voting and investment power with respect to all shares of common stock, Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock beneficially owned by him, her or it, (ii) the number of shares of common stock beneficially owned by each stockholder shown above has been determined in accordance with Rule 13d-3 under the Exchange Act and includes, for such purpose, shares of common stock that such stockholder has the right to acquire within 60 days of January 9, 2020 after giving effect to any applicable limitations on beneficial ownership described in the footnotes below, or Beneficial Ownership Limitation, and (iii) the beneficial ownership percentages shown above are based on 68,556 shares of common stock, 32,061 shares of Series E Preferred Stock, and 9,399 shares of Series E-1 Preferred Stock outstanding as of January 9, 2020, respectively. Shares of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock vote together with the common stock on an as-converted basis,

subject to any applicable Beneficial Ownership Limitation, on all matters submitted to holders of common stock for approval.

(2) Includes 500 shares of common stock, which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(3) The 147 shares of Series E Convertible Preferred Stock are convertible into 5,797 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 5,797 shares of common stock that may be obtained by Dr. Simpson upon the exercise of a warrant held by her, which is subject to the Beneficial Ownership Limitation.

(4) Includes 357 shares of common stock, which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(5) The 68 shares of Series E Convertible Preferred Stock are convertible into 2,684 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,684 shares of common stock that may be obtained by Ms. Keck upon the exercise of a warrant held by her, which is subject to the Beneficial Ownership Limitation.

(6) Includes 357 shares of common stock, which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(7) The 65 shares of Series E Convertible Preferred Stock are convertible into 2,564 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,564 shares of common stock that may be obtained by Mr. Purpura upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(8) Includes 118 shares of common stock, which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(9) The 93 shares of Series E Convertible Preferred Stock are convertible into 3,669 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 3,669 shares of common stock that may be obtained by Mr. Stoll upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(10) Includes 118 shares of common stock, which Mr. Rueckert has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(11) The 60 shares of Series E Convertible Preferred Stock are convertible into 2,367 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,367 shares of common stock that may be obtained by Mr. Rueckert upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(12) Includes 118 shares of common stock, which Dr. Taglietti has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 9, 2020.

(13) The 60 shares of Series E Convertible Preferred Stock are convertible into 2,367 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,367 shares of common stock that may be obtained by Mr. Taglietti upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(14) Includes 1,640 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 January 9, 2020.

(15) The aggregate 493 shares of Series E Convertible Preferred Stock are convertible into an aggregate of 19,448 shares of common stock subject to the Beneficial Ownership Limitation and does not include the aggregate 19,448 shares of common stock that may be obtained by such persons upon the exercise of warrants held by them, subject to the Beneficial Ownership Limitation.

(16) The information provided is based on a Statement on Schedule 13G jointly filed on July 15, 2019 by and on behalf of each of Altium Growth Fund, LP, Altium Capital Management, LP, and Altium Growth GP, LLC which acquired shares of Series E Preferred Stock and warrants in our July 2019 PIPE Financing. Altium Growth Fund, LP is the record and direct beneficial owner of the securities referenced. Altium Capital Management, LP is the investment adviser of, and may be deemed to beneficially own securities, owned by, Altium Growth Fund, LP. Altium Growth GP, LLC is the general partner of, and may be deemed to beneficially own securities owned by, Altium Growth Fund, LP. The reporting persons hold shared voting and dispositive power with respect to 2,300 shares of Series E Convertible Preferred Stock and 1,100 shares

of Series E-1 Convertible Preferred Stock which could be converted into 134,074 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock subject to the Blockers described below. The referenced securities do not include 134,074 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Each of the reporting persons may be deemed to be a member of a group with respect to Delcath or securities of Delcath for the purposes of Section 13(d) or 13(g) of the Securities Act of 1933, as amended. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) the as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of January 9, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock, the Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

(17) The information provided is based on a Statement on Schedule 13G jointly filed on August 1, 2019 by and on behalf of Rosalind Advisors, Inc., Rosalind Opportunities Fund I L.P., Rosalind Master Fund L.P. and Steven Salamon with respect to beneficial ownership of shares of Series E Convertible Preferred Stock and warrants acquired in our July 2019 PIPE Financing. Rosalind Advisors, Inc., or the Advisor, is the investment advisor to Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. and may be deemed to be the beneficial owner of shares held by Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. Steven Salamon is the portfolio manager of the Advisor and may be deemed to be the beneficial owner of shares of Series E Convertible Preferred Stock and underlying warrants for common stock held by Rosalind Master Fund L.P. The Rosalind Opportunities Fund I L.P. holds shared voting and dispositive power with respect to 10,400 shares of Series E Convertible Preferred Stock and 2,260 shares of Series E-1 Convertible Preferred Stock that can be converted into 499,228 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock subject to the Blockers described below. The Rosalind Master Fund L.P. holds shared dispositive and voting power with respect to 6,400 shares of Series E Convertible Preferred Stock and 615 shares of Series E-1 Convertible Preferred Stock that could be converted into 276,627 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock subject to the Blockers described below. The Advisor and Steven Salamon hold shared voting and dispositive power with respect to 19,675 shares of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock that could be converted into 775,855 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock subject to the Blockers described below. Notwithstanding the foregoing, the Advisor and Mr. Salamon disclaim beneficial ownership of any such shares. The referenced securities do not include 775,855 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Each of the reporting persons may be deemed to be a member of a group with respect to Delcath or securities of Delcath for the purposes of Section 13(d) or 13(g) of the Securities Act of 1933, as amended. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock or the Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise,

more than 4.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of January 9, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

(18) Based on the information available to the Company, Hudson Bay Master Fund Ltd, which acquired shares of Series E Convertible Preferred Stock, Series E-1 Convertible Preferred Stock, Series E Warrants and Series E-1 Warrants in our July and August 2019 PIPE financings. Hudson Bay Master Fund Ltd is the record and direct beneficial owner of the securities referenced. Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Hudson Bay Capital Management LP may be deemed to be the beneficial owner of all shares of common stock underlying the securities held by Hudson Bay Master Fund Ltd. Mr. Gerber disclaims beneficial ownership of these securities. Hudson Bay Capital Management LP holds sole voting and dispositive power with respect to 2,187 shares of Series E Convertible Preferred Stock could be converted into 86,247 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock subject to the Blockers described below. The referenced securities do not include 97,093 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 9.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of January 9, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock, Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Transactions with Related Persons. We have adopted a written policy for the review and approval or ratification of transactions between our company 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 our 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 us, 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 our common stock, or immediate family member of any of such persons.

Except for the participation of certain Related Parties in the Private Placements and the Debt Exchange, no Related Party transactions occurred during 2019 and 2018.

DESCRIPTION OF SECURITIES

The following description of our common stock and preferred stock summarizes the material terms and provisions of our common stock and preferred stock. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation, as amended, as our certificate of incorporation, and we refer to our Amended and Restated By-Laws as our by-laws. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 1,000,000,000 shares of common stock, $0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.01 par value per share. As of January 9, 2020, we had 68,556 shares of common stock outstanding and 32,061 shares of Series E Convertible Preferred Stock and 9,399 shares of Series E-1 Convertible Preferred Stock outstanding. As of January 9, 2020, we had 1.7 million shares of common stock issuable upon the exercise of outstanding warrants, including (i) 29 Common Stock Warrants and (ii) 1.7 million Series E and Series E-1 Warrants at a weighted average exercise price of $25.36 per share.

Common Stock

Voting

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder’s shares of common stock. If we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Preferred Stock

Our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval, of which Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock or, collectively, the Preferred Stock, is outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the designation and powers, rights and preferences and the qualifications, limitations, or restrictions with respect to each class or series of such class without further vote or action by the stockholders. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

In connection with the July 11, 2019 Private Placement, the Company filed a certificate of designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock with the Secretary of State of the State of Delaware, or the Delaware SOS, for the purpose of amending its Amended and Restated Certificate of Incorporation to classify and designate 40,000 authorized but unissued shares of the Company's preferred stock as shares of Series E Preferred Stock. The preferences, conversion and other rights, voting powers, restrictions, limitations as to dividends and other distributions, qualifications and terms and conditions of redemption of the Series E Convertible Preferred Stock are set forth in the Certificate of Designation and are described below. The certificate of designation became effective on July 11, 2019 upon acceptance for filing by the Delaware SOS.

In connection with the August 15, 2019 Private Placement, the Company filed a certificate of designation of Preferences, Rights and Limitations of Series E-1 Convertible Preferred Stock with Delaware SOS, for the purpose of amending its Amended and Restated Certificate of Incorporation to classify and designate 12,960 authorized but unissued shares of the Company's preferred stock as shares of Series E-1 Convertible Preferred Stock. The preferences, conversion and other rights, voting powers, restrictions, limitations as to dividends and other distributions, qualifications and terms and conditions of redemption of the Series E-1 Convertible Preferred Stock are set forth in the certificate of designation and are described below. The certificate of designation became effective on August 15, 2019 upon acceptance for filing by the Delaware SOS.

Each share of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock has a par value of $0.01 per share and a stated value equal to $1,000, or the Stated Value, and is convertible at any time at the option of the holder into the number of shares of common stock determined by dividing the stated value by the conversion price of $25.36, subject to certain limitations and adjustments, or the Conversion Price. Except for certain adjustments, the holders of Preferred Stock will be entitled to receive dividends on shares of Preferred Stock equal (on an as if converted basis) to and in the same form as dividends paid on shares of the common stock. Any such dividends that are not paid to the holders of Preferred Stock will increase the Stated Value. No other dividends will be paid on shares of Preferred Stock. The Preferred Stock will vote on an as converted basis on all matters submitted to the holders of common stock for approval, subject to certain limitations and exceptions. The affirmative vote of the holders of a majority of the then outstanding shares of Preferred Stock is required to increase the number of authorized shares of Preferred Stock or to alter or change adversely the powers, preferences or rights given to the Preferred Stock, or to amend the Company's organizational documents in any manner that adversely affects the rights of the holders of the Preferred Stock. Upon any liquidation of the Company, the holders of Preferred Stock will be entitled to receive out of the assets of the Company an amount equal to the Stated Value plus any accrued and unpaid dividends thereon for each share of Preferred Stock before any distribution or payment will be made to the holders of the common stock.

Reset Provision

Pursuant to the terms of the Preferred Stock and the 2019 Warrants, the Conversion Price of the Preferred Stock and the Exercise Price of the 2019 Warrants were initially subject to adjustment in each of the following circumstances: (i) on the third trading day following the date that the Company effects a reverse stock split, or the Reverse Split Reset Date, (ii) the date that the initial registration statement covering the shares of common stock issuable upon the conversion of the Preferred Stock and the exercise of the 2019 Warrants is declared

effective by the SEC, or the Registration Reset Date, and (iii) in the event that all of the shares of common stock which we were required to register with the SEC were not then registered on an effective registration statement, the date that all of the shares underlying the respective Preferred Stock and 2019 Warrants may be sold pursuant to Rule 144, or the Rule 144 Reset Date, each of such reset dates, a Reset Date and, collectively, the Reset Dates. On each Reset Date, the Conversion Price and the Exercise Price were to be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price or Exercise Price, as applicable, and (y) 90% of the average of the five daily volume weighted average prices of the common stock immediately prior to each Reset Date, or the Reset Formula. In the event of a reduction in the Exercise Price, the aggregate number of Warrant Shares issuable upon the exercise of the 2019 Warrants were to be increased such that the aggregate Exercise Price of the Warrants on the day immediately following such Reset Date equaled the aggregate Exercise Price immediately prior to such adjustment. In addition, from the date of issuance of the Preferred Stock and Warrants until such time that the Company's common stock is listed or quoted on a national exchange, the Conversion Price and the Exercise Price are subject to price-based anti-dilution protections.

The Registration Reset Date occurred on November 7, 2019. However, pursuant to the Reset Formula, no reduction in the Conversion Price or the Exercise Price occurred on the Registration Reset Date. The Reverse Split Reset Date occurred on December 30, 2019. Pursuant to the Reset Formula, the Conversion Price and the Exercise Price were reduced to $25.36 per share as of the Reverse Split Reset Date. The Rule 144 Reset Date with respect to the Series E Preferred Stock and the Series E Warrants will occur on January 15, 2020, and we do not expect any reset in the Conversion Price or the Exercise Price of the Series E Preferred Stock or the Series E Warrants to occur as of such date because all of the shares of common stock issuable in respect of such securities have been registered for resale. The Rule 144 Reset Date with respect to the Series E-1 Preferred Stock and the Series E-1 Warrants will occur on February 19, 2020. Based on the assumed public offering price of $17.00 per share, the closing sale price per share of our common stock on the OTCQB on January 9, 2020, we do not expect any reset in the Conversion Price or the Exercise Price of the Series E-1 Preferred Stock or the Series E-1 Warrants to occur as of such date because all of the shares of common stock issuable in respect of such securities have been registered for resale. However, if the public offering price is less than $16.10 per share, a reset of the Conversion Price of the Series E-1 Preferred Stock and the Exercise Price of the Series E-1 Warrants could occur which could require us to issue additional shares of common stock upon the conversion of the Series E-1 Preferred Stock and the exercise of the Series E-1 Warrants, unless the holders of such securities agree to waive their right to such reset.

Warrants

The following is a brief summary of material provisions of the warrants related to the shares of common stock offered for resale and issuable upon the exercise of such warrants issued to the Selling Stockholders described herein.

Pursuant to the Securities Purchase Agreements dated July 11, 2019 and August 15, 2019, the Company issued warrants, or the 2019 Warrants, to purchase a number of shares of common stock equal to the number of shares of common stock issuable upon conversion of the Preferred Stock purchased. Each 2019 Warrant has an exercise price equal to $25.36, subject to adjustment in accordance with the terms of the 2019 Warrants, or the Exercise Price, and will be exercisable at any time beginning on the date that the Company effects a reverse stock split until 5:00 p.m. (NYC time) on the date that is five years following the Reverse Split Reset Date.

As noted above under "Description of Securities—Preferred Stock—Reset Provision", the 2019 Warrants are also subject to reset in certain circumstances.

Market Information

Our common stock is quoted the OTCQB under the symbol “DCTH”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

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 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 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.

UNDERWRITING

We have entered into an underwriting agreement, dated , 2020, with Roth Capital Partners, LLC, who we refer to as the underwriter, with respect to the shares of common stock subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, the number of shares of common stock provided below.

Underwriter	Number of Shares
Roth Capital Partners, LLC	
Aegis Capital Corp.	
Total	

The underwriter is offering the shares of common stock subject to its acceptance of the shares of common stock from us and subject to prior sale. The underwriting agreement provides that the obligation of the underwriter to pay for and accept delivery of the shares of common stock offered by this prospectus is subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriter is obligated to take and pay for all of the shares of common stock if any such shares are taken. However, the underwriter is not required to take or pay for the shares of common stock covered by the underwriter's over-allotment option described below.

Over-Allotment Option

We have granted the underwriter an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of additional shares of common stock to cover over-allotments, if any, at the public offering price set forth on the cover page of this prospectus, less the underwriting discount. The underwriter may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. If the underwriter exercises this option, the underwriter will be obligated, subject to certain conditions, to purchase a number the additional shares for which the option has been exercised.

Discount, Commissions and Expenses

The underwriter has advised us that it proposes to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. The underwriter may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share to certain brokers and dealers. After this offering, the public offering price, concession and reallowance to dealers may be changed by the underwriter. No such change will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The shares of common stock are offered by the underwriter as stated herein, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. The underwriter has informed us that it does not intend to confirm sales to any accounts over which it exercises discretionary authority.

The following table shows the underwriting discount payable to the underwriter by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriter's over-allotment option to purchase additional shares.

	Per share	Total Without Exercise of Over-Allotment Option	Total With Exercise of Over-Allotment Option
Public offering price	$	$	$
Underwriting discount (7%)	$	$	$

We have agreed to reimburse the underwriter for certain out-of-pocket expenses, including the fees and disbursements of its counsel, up to an aggregate of $75,000. We estimate that the total expenses payable by us in connection with this offering, other than the underwriting discount referred to above, will be approximately $275,000.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Lock-Up Agreements

We, our officers, directors and certain of our stockholders have agreed to, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the underwriter. The underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase, which creates a short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any covered short position by either exercising its over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If the underwriter sells more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit a syndicate representative to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids, to the extent applicable, may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a

decline in the market price of the common stock. As a result, the price of our securities may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriter makes any representations that the underwriter will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

NASDAQ Listing Application

Our shares of common stock are quoted on the OTCQB under the symbol "DCTH." We have applied to list our common stock on The NASDAQ Capital Market under the symbol "DCTH." We will not consummate this offering unless our common stock is approved for listing on The NASDAQ Capital Market.

Electronic Distribution

This preliminary prospectus in electronic format may be made available on websites or through other online services maintained by the underwriter, or by its affiliates. Other than this preliminary prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of this preliminary prospectus or the registration statement of which this preliminary prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other

From time to time, the underwriter and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees. In the course of their businesses, the underwriter and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriter and its affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering and except as described below, the underwriter has not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain the underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus. In connection with the August 2019 Private Placement, we paid the underwriter a commission of $580,434.

Selling Restrictions

No action may be taken in any jurisdiction other than the United States that would permit a public offering of the common stock or the possession, circulation or distribution of this prospectus in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither the prospectus nor any other offering material or advertisements in connection with the common stock may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

Notice to Prospective Investors in Canada

The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in the European Union

In relation to each Member State of the European Union, or a Relevant Member State, no offer of common stock may be made to the public in that Relevant Member State other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common stock shall require us or the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any common stock being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any common stock to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

We, the underwriter and its affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of common stock in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of common stock. Accordingly, any person making or intending to make an offer in that Relevant Member State of common stock which are the subject of the offering contemplated in this prospectus supplement may only do so in circumstances in which no obligation arises for us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of common stock in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer.

Notice to Prospective Investors in the United Kingdom

In the United Kingdom, this prospectus supplement is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons").

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this prospectus supplement or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this prospectus supplement relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon by Lowenstein Sandler LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements as of December 31, 2018 and for the year then ended included in this prospectus and in the registration statement have been so included in reliance on the report of Marcum LLP, an independent registered public accounting firm, (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

The consolidated financial statements as of December 31, 2017 and for the year then ended included in this prospectus and in the registration statement have been so included in reliance on the report of Grant Thornton LLP, an independent registered public accounting firm, (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

WHERE TO FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. You may also request a copy of these filings, at no cost, by writing us at:

Delcath Systems, Inc.
1633 Broadway, Suite 22C
New York, New York 10019
Attn: Barbra C. Keck, Corporate Secretary
E-Mail: investorrelations@delcath.com
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We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.delcath.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Delcath Systems, Inc. and Subsidiaries (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 financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, 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 1. 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 provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

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

NEW YORK, NEW YORK, June 14, 2019 (except for the reverse stock split described in Note 2 and Note 15, as to which the date is December 30, 2019)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders 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.

Going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2017 consolidated financial statements, the Company has incurred recurring losses from operations and as of December 31, 2017 has an accumulated deficit of $324.8 million. These conditions, along with other matters as set forth in Note 1 to the 2017 consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also discussed in Note 1 to the 2017 consolidated financial statements. 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 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 reverse stock splits described in Note 2, as to which the date is May 2, 2018 and December 24, 2019, respectively)

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

	December 31, 2018	December 31, 2017
Assets		
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	$ 6,844	$ 8,887
Liabilities and Stockholders' Equity (Deficit)		
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	21,783	8,209
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; 14,715 and 377 shares issued and 14,715 and 376 shares outstanding at December 31, 2018 and December 31, 2017, respectively*	—	—
Additional paid-in capital	329,065	325,519
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)	$ 6,844	$ 8,887

* reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

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*	$ (504.00)	$ (2,275,000)
Weighted average number of basic and diluted shares outstanding*	38,151	21

* reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

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	1	—	—	—	(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	375	—	—	—	—	—	40,121	—	—	40,121
Fair value of beneficial conversion feature of convertible note	—	—	—	—	—	—	4,908	—	—	4,908
Series B preferred stock dividend	—	—	—	—	—	—	—	(527)	—	(527)
Warrants exercised	1	—	—	—	—	—	19	—	—	19
Fair value of warrants exercised	—	—	—	—	—	—	2,552	—	—	2,552
Adjustment for rounding related to Nov 2017 reverse stock split	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(45,117)	—	(45,117)
Foreign currency translation	—	—	—	—	—	—	—	—	83	83
Balance at December 31, 2017	377	—	—	—	(1)	(51)	325,519	(324,832)	42	678
Compensation income related to cancellation of stock options	—	—	—	—	—	—	(40)	—	—	(40)
Compensation expense for issuance of restricted stock	236	—	—	—	—	—	98	—	—	98
Sale of Common Stock, net of expenses	7,624	—	—	—	—	—	10,916	—	—	10,916
Fair value of warrants issued in Feb 2018 public offering	—	—	—	—	—	—	(18,306)	—	—	(18,306)
Cashless exercise of warrants	49	—	—	—	—	—	—	—	—	—
Issuance of pre-funded warrants	—	—	—	—	—	—	520	—	—	520
Exercise of pre-funded warrants	5,250	—	—	—	—	—	—	—	—	—
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	1,179	—	—	—	—	—	—	—	—	—
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	14,715	—	101	—	—	—	329,065	(344,054)	50	(14,939)

* reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31, 2018	2017
Cash flows from operating activities:		
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	(14,732)	(15,398)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(76)	(524)
Net cash (used in) provided by investing activities	(76)	(524)
Cash flows from financing activities:		
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	13,236	(10,517)
Foreign currency effects on cash, cash equivalents and restricted cash	(174)	67
Net decrease in cash, cash equivalents and restricted cash	(1,746)	(26,372)
Cash, cash equivalents and restricted cash:		
Beginning of period	5,324	31,696
End of period	$ 3,578	$ 5,324
Supplemental non-cash activities:		
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, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

(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 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.

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.

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:

(in thousands, except share data)	December 31, 2018	2017
Net loss—basic	$(19,222)	$ (45,117)
Preferred stock dividends	—	(527)
Net loss—diluted	$(19,222)	$ (45,644)
Weighted average shares outstanding—basic	38,151	21
Weighted average shares outstanding—diluted	38,151	21
Net loss per share—basic	$(504.00)	$(2,275,000)
Net loss per share—diluted	$(504.00)	$(2,275,000)

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.

At December 31, 2018, the Company has 0.1 million pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation at December 31, 2018:

	December 31, 2018
Weighted average shares issued	3,913
Weighted average pre-funded warrants	34,238
Weighted average shares outstanding	38,151

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:

	2018	2017
Common stock warrants—equity	6,005	21
Common stock warrants—liability	271	—
Assumed conversion of convertible notes	3,681	—
Total	9,957	21

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.

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 go r 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.

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.

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

(5) INVENTORIES

Inventories consist of:

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

(6) PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets include the following:

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

1 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.

(7) PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consists of:

(in thousands)	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	$ 925	$ 1,298	

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:

(in thousands)	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
Other1	1,275	985
Total accrued expenses	$ 7,964	$ 3,408

1 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:

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

(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 $1,225 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 6,005 Series D Warrants with exercise prices ranging from $1,225—$2,800 and 0.1 million Pre-Funded Series D Warrants with a purchase price of $7.00. 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:

	June 2018 Series D Warrant	June 2018 Pre-Funded Series D Warrants
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 $1,225, 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 18,506 to 31,724 and the total number of July 2018 Pre-Funded Warrants was increased from 13,207 to 22,640. 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.

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

(in millions)	Interest rate	Conversion price	Principal	Unamortized Discount	Carrying value
December 4, 2018	8.0%	$ 1,225	$ 1.7	$ —	$ 1.7
March 1, 2019	8.0%	1,225	0.6	(0.5)	0.1
March 21, 2019	8.0%	1,225	0.4	(0.2)	0.2
December 4, 2019	8.0%	1,225	0.9	(0.9)	—
March 1, 2020	8.0%	1,225	0.8	(0.8)	—
March 21, 2020	8.0%	1,225	0.1	(0.1)	—
Total Convertible Notes Payable, net			$ 4.5	$ (2.5)	$ 2.0

(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 2,366 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 606 shares of its Common Stock, 109 pre-funded warrants and the issuance of warrants to purchase 1,429 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 $7,000 per share with 273 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 $7,000; 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 6,669 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 1,179 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.

Pre-Funded Series D Warrant Exercises

5,379 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 shares 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 eligibility to use Form S-3 due to the late filing of its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and its late filing of its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019.

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 2,142 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 1,782 shares of Common Stock, at an exercise price of $196.70 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	1	$ 197,225,000 - $13,798,400,000	$ 637,218,564	5.59
Warrants issued	21		1,610,000	
Warrants exercised	(1)		2,954,000	
Warrants expired	(1)		591,675,000	
Outstanding at December 31, 2017	20	$ 857,500 - $13,798,400,000	$ 4,868,205,366	4.88
Warrants issued in Feb 2018 registered direct offering	1,538		6,531	
Warrants issued with convertible notes	98,814		126	
Exercised	(6,536)		1,252	
Expired	(1)		13,798,400,000	
Outstanding at December 31, 2018	93,835	$ 7.00 - $7,000	$ 150.67	5.75

(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

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2018	2017	2018	2017	2018	2017	2018	2017
Liabilities								
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)

(in thousands)	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

(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:

(in thousands)	Future Lease Payment
2019	885
2020	916
2021	348
	$ 2,149

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 our 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.

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:

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

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

(in thousands)	Year Ended December 31, 2018	2017
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
	$ —	$ —

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

(in thousands)	Year Ended December 31, 2018	2017
Deferred tax assets:		
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	11,364	5,985
Deferred tax liabilities:		
Beneficial conversion feature	—	—
Other	—	13
Total deferred tax liabilities		13
Valuation allowance	11,364	5,972
Net deferred tax assets	$ —	$ —

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.

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:

(in thousands)	December 31, 2018	December 31, 2017
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	$ 11,364	$ 5,972

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.

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 11,285 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 $1,225 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 sale 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 sale 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.

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 5,605 Series D Warrants and 0.1 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 $2.0 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants.

On December 24, 2019, the Company effected a reverse stock split at which time Delcath's common stock began trading on the OTCQB on a one-for-seven hundred (1:700) split-adjusted basis. All owners of record as of the open of the OTCQB market on December 24, 2019 received one issued and outstanding share of Delcath common stock in exchange for seven hundred outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-seven hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company's consolidated financial statements and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

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

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 15,334	$ 2,516
Restricted cash	181	1,062
Accounts receivables, net	12	585
Inventories	736	858
Prepaid expenses and other current assets	864	898
Total current assets	17,127	5,919
Property, plant and equipment, net	756	925
Right-of-use assets	1,012	—
Total assets	$ 18,895	$ 6,844
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 4,871	$ 7,715
Accrued expenses	6,537	7,964
Convertible notes payable, net of debt discount	—	2,038
Lease liabilities, current portion	656	—
Warrant liability	20,410	33
Total current liabilities	32,474	17,750
Deferred revenue	2,890	3,405
Lease liabilities, long-term portion	356	—
Convertible notes payable, long-term	2,000	—
Other non-current liabilities	—	628
Total liabilities	37,720	21,783
Commitments and contingencies	—	—
Stockholders' deficit		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 42,082 shares and 101 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 26,112 and 14,715 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively*	—	—
Additional paid-in capital	364,750	329,065
Accumulated deficit	(383,664)	(344,054)
Accumulated other comprehensive income	89	50
Total stockholders' deficit	(18,825)	(14,939)
Total liabilities and stockholders' deficit	$ 18,895	$ 6,844

* reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018 and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Product revenue	$ 216	$ 824	$ 528	$ 2,384
Other revenue	164	—	535	—
Cost of goods sold	(172)	(233)	(440)	(600)
Gross profit	208	591	623	1,784
Operating expenses:				
Selling, general and administrative	4,002	2,279	9,204	7,286
Research and development	1,778	4,106	6,789	13,886
Total operating expenses	5,780	6,385	15,993	21,172
Operating loss	(5,572)	(5,794)	(15,370)	(19,388)
Change in fair value of the warrant liability, net	434	1,198	451	18,407
Loss on debt extinguishment	—	(1,123)	—	(1,123)
Loss on issuance of financial instrument	(1,714)	—	(1,721)	(2,826)
Interest expense	(671)	(3,151)	(4,735)	(3,402)
Other income (expense)	4	(10)	4	(21)
Net (loss) income	$ (7,519)	$ (8,880)	$ (21,371)	$ (8,353)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	89	105	39	63
Total other comprehensive (loss) income	$ (7,430)	$ (8,775)	$ (21,332)	$ (8,290)
Common share data:				
Basic loss per common share*	$ (287.00)	$ (175.00)	$ (924.00)	$ (420.00)
Diluted loss per common share*	$ (987.00)	$ (175.00)	$ (1,715.00)	$ (448.00)
Weighted average number of basic shares outstanding*	26,112	51,229	23,095	19,841
Weighted average number of diluted shares outstanding*	26,112	51,229	23,095	19,841

* reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018 and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Common Stock $0.01 Par Value		Preferred Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at January 1, 2019	14,715	$ —	101	$ —	$329,065	$ (344,054)	$ 50	$(14,939)
Compensation expense for issuance of stock options	—	—	—	—	54	—	—	54
Compensation expense for issuance of restricted stock	20	—	—	—	4	—	—	4
Issuance of Series D Preferred Stock	—	—	15	—	150	—	—	150
Retirement of Series D Preferred Stock	—	—	(116)	—	(1,160)	—	—	(1,160)
Exercise of Pre-Funded Series D Warrants	5,885	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(7,894)	—	(7,894)
Total comprehensive loss	—	—	—	—	—	—	7	7
Balance at March 31, 2019	20,620	$ —	—	$ —	$328,113	$ (351,948)	$ 57	$(23,778)
Compensation expense for issuance of stock options	—	—	—	—	75	—	—	75
Exercise of Pre-Funded Series D Warrants	5,400	—	—	—	—	—	—	(1)
Exchange of warrants	92	—	—	—	14	—	—	14
Net loss	—	—	—	—	—	(5,959)	—	(5,959)
Total comprehensive loss	—	—	—	—	—	—	(80)	(80)
Balance at June 30, 2019	**26,112**	**$ —**	**—**	**$ —**	**$328,201**	**$ (357,907)**	**$ (23)**	**$(29,729)**
Compensation expense for issuance of stock options	—	—	—	—	70	—	—	70
Issuance of Series E Preferred Stock	—	—	32,572	—	42,915	(13,340)	—	29,575
Issuance of Series E-1 Preferred Stock	—	—	9,510	—	14,408	(4,898)	—	9,510
Fair value of warrants issued	—	—	—	—	(20,844)	—	—	(20,844)
Net loss	—	—	—	—	—	(7,519)	—	(7,519)
Total comprehensive loss	—	—	—	—	—	—	112	112
Balance at September 30, 2019	**26,112**	**$ —**	**42,082**	**$ —**	**$364,750**	**$ (383,664)**	**$ 89**	**$(18,825)**

	Common Stock Issued $0.01 Par Value		Treasury Stock					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2018	377	$ —	(1)	$ (51)	$325,519	$ (324,832)	$ 42	$ 678
Compensation expense for issuance of stock options	—	—	—	—	7	—	—	7
Compensation expense for issuance of restricted stock	—	—	—	—	14	—	—	14
Sale of common stock, net of expenses	956	—	—	—	4,251	—	—	4,251
Fair value of warrants issued	—	—	—	—	(18,306)	—	—	(18,306)
Net income	—	—	—	—	—	7,185	—	7,185
Total comprehensive loss	—	—	—	—	—	—	(34)	(34)
Balance at March 31, 2018	1,333	$ —	(1)	$ (51)	$311,485	$ (317,647)	$ 8	$ (6,205)
Compensation expense for issuance of stock options	—	—	—	—	(47)	—	—	(47)
Compensation expense for issuance of restricted stock	—	—	—	—	(95)	—	—	(95)
Sale of common stock, net of expenses	—	—	—	—	(41)	—	—	(41)
Net income	—	—	—	—	—	(6,658)	—	(6,658)
Total comprehensive loss	—	—	—	—	—	—	(44)	(44)
Balance at June 30, 2018	**1,333**	**$ —**	**(1)**	**$ (51)**	**$311,302**	**$ (324,305)**	**$ (36)**	**$(13,090)**
Compensation expense for issuance of restricted stock	86	—	—	—	116	—	—	116
Sale of common stock, net of expenses	6,669	—	—	—	7,067	—	—	7,067
Issuance of pre-funded warrants	—	—	—	—	520	—	—	520
Cashless exercise of warrants	50	—	—	—	—	—	—	—
Fair value of warrants issued with convertible notes	—	—	—	—	5,007	—	—	5,007
Fair value of warrants reclassified from liability to equity	—	—	—	—	4,210	—	—	4,210
Beneficial conversion feature of convertible notes	—	—	—	—	44	—	—	44
Net loss	—	—	—	—	—	(8,880)	—	(8,880)
Total comprehensive loss	—	—	—	—	—	—	141	141
Balance at September 30, 2018	**8,138**	**$ —**	**(1)**	**$ (51)**	**$328,266**	**$ (333,185)**	**$ 105**	**$ (4,865)**

* reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018 and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine months ended September 30, 2019	2018
Cash flows from operating activities:		
Net (loss) income	$ (21,371)	$ (8,353)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	199	(40)
Restricted stock compensation expense	4	35
Depreciation expense	168	342
Amortization of right of use assets	1,535	—
Warrant liability fair value adjustment	(451)	(18,407)
Non-cash interest income	(23)	(2)
Equitization of expenses	1,474	—
Loss on issuance of financial instrument	1,715	2,826
Interest expense accrued related to convertible notes	33	—
Debt discount amortization	4,467	3,381
Loss on debt extinguishment	—	1,123
Changes in assets and liabilities:		
Prepaid expenses and other assets	43	171
Accounts receivable	564	(60)
Inventories	85	289
Accounts payable and accrued expenses	(4,289)	5,662
Deferred revenue	(360)	—
Interest payments of financing leases	(3)	—
Payments on operating leases	(1,485)	—
Other non-current liabilities	(627)	139
Net cash used in operating activities	(18,322)	(12,894)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2)	(59)
Net cash used in investing activities	(2)	(39)
Cash flows from financing activities:		
Net proceeds from the issuance of debt	3,719	—
Net proceeds from sale of Series E Preferred Stock and warrants	26,510	—
Net proceeds from sale of Series D Preferred Stock	150	—
Principal payments on financing leases	(49)	—
Net proceeds from sale of common stock and warrants	—	11,797
Net proceeds from convertible debt financing	—	5,727
Net cash provided by financing activities	30,330	17,524
Foreign currency effects on cash, cash equivalents and restricted cash	(69)	80
Net decrease in cash, cash equivalents and restricted cash	11,937	4,651
Cash, cash equivalents and restricted cash:		
Beginning of period	3,578	5,324
End of period	$ 15,515	$ 9,975
Supplemental non-cash financing activities:		
Fair value of warrants issued	$ 20,844	$ 28,539

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to the Condensed Consolidated Financial Statements

(1) GENERAL

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. ("Delcath" or the "Company") as of and for the three and nine months ended September 30, 2019 and 2018 should be read in conjunction with the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "Annual Report") which was filed with the Securities Exchange Commission (the "SEC") on June 14, 2019 and may also be found on the Company's website (www.delcath.com). In these notes to the condensed consolidated financial statements the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System ("Melphalan/HDS")—is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our system is commercially available under the trade name Delcath Hepatic CHEMOSAT ® Delivery System for Melphalan ("CHEMOSAT") where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our clinical development program ("CDP") 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 CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials ("IITs").

Liquidity and Operating Matters

The accompanying interim condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and expects to continue incurring losses for the next several years. These losses, among other factors, raise substantial doubt about the Company's ability to continue as a going concern.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

Basis of Presentation

These interim condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the SEC's instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all entities controlled by Delcath and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim condensed consolidated financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and

cash flows for the interim periods ended September 30, 2019 and 2018; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 Summary of Significant Accounting Policies to the Consolidated Financial Statements included in the Company's Annual Report filed for the fiscal year ended December 31, 2018.

Derivative Financial Instruments

The accounting treatment of derivative financial instruments requires that the Company record financial instruments at their fair value as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. As a result of issuing such instruments the Company has adopted a sequencing policy in accordance with ASC 815-40-35-12 whereby all future instruments may be classified as a derivative liability with the exception of instruments related to share-based compensation issued to employees. However, the Company has recognized the Series E Preferred Stock and Series E-1 Preferred Stock issued in July 2019 and August 2019 as equity because the agreements related to the issuance of those instruments specifically state that the common shares underlying the Preferred Stock take priority in registration. Additionally, the Company has a sufficient number of authorized shares for the issuance of common shares upon the conversion of the Preferred Stock. The Company did not have sufficient authorized shares to settle the associated warrants and accordingly has classified such warrants as a liability in the accompanying financial statements.

Recently Adopted Accounting Pronouncements

In February 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220). ASU 2018-02 allows a company to elect a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. ASU 2018-02 is effective for periods beginning after December 15, 2018. Upon adoption of ASU 2018-02, the Company did not elect to reclassify the tax effects of the Tax Cuts and Jobs Act from accumulated other comprehensive income to retained earnings, as the stranded tax effects were insignificant.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) effective January 1, 2019, electing the practical expedients and applying the transition provisions as of the effective date. Reporting periods beginning on or after January 1, 2019 are presented under Topic 842, while prior period amounts, as reported under previous GAAP, were not adjusted. The adoption of Topic 842 on January 1, 2019 did not have a significant impact on the Company's consolidated results of operations or cash flows.

(2) 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 sheets. Restricted cash does not include required minimum balances.

Cash, cash equivalents, and restricted cash balances were as follows:

(in thousands)	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 15,334	$ 2,516
Letters of credit	131	1,012
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 15,515	$ 3,578

(3) INVENTORIES

Inventories consist of the following:

(in thousands)	September 30, 2019	December 31, 2018
Raw materials	$ 351	$ 358
Work-in-process	350	500
Finished goods	35	—
Total inventories	$ 736	$ 858

(4) PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

(in thousands)	September 30, 2019	December 31, 2018
Clinical trial expenses	$ 500	$ —
Insurance premiums	54	140
Security deposit	50	51
Income tax and VAT receivable	33	579
Other[1]	227	128
Total prepaid expenses and other current assets	$ 864	$ 898

1 Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at September 30, 2019 and December 31, 2018.

(5) PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consist of the following:

(in thousands)	September 30, 2019	December 31, 2018	Estimated Useful Life
Buildings and land	$ 589	$ 589	30 years - Buildings
Enterprise hardware and software	1,739	1,742	3 years
Leaseholds	1,687	1,701	Lesser of lease term or estimated useful life
Equipment	1,002	1,002	7 years
Furniture	197	198	5 years
Property, plant and equipment, gross	5,214	5,232	
Accumulated depreciation	(4,458)	(4,307)	
Property, plant and equipment, net	$ 756	$ 925	

Depreciation expense for the three and nine months ended September 30, 2019 was approximately $0.1 million and $0.2 million, respectively as compared to approximately $0.1 million and $0.3 million, respectively, for the same periods in 2018.

(6) ACCRUED EXPENSES

Accrued expenses consist of the following:

(in thousands)	September 30, 2019	December 31, 2018
Compensation, excluding taxes	$ 3,274	$ 1,785
Clinical trial expenses	2,590	4,530
Interest payable	33	402
Other[1]	640	1,247
Total accrued expenses	$ 6,537	$ 7,964

1 Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at September 30, 2019 and December 31, 2018.

(7) LEASES

The Company recognizes right-of-use (“ROU”) assets and lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve months. The Company leases its facilities under non-cancellable operating and financing leases.

The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the ROU asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company’s leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments.

The following table summarizes the Company's operating and financing leases as of and for the nine months ended September 30, 2019:

(in thousands)	U.S.	Ireland	Total
Lease cost			
Operating lease cost	$ 592	$ 160	$ 752
Financing lease cost	32	—	32
Sublease income	(215)	(133)	(348)
Total	$ 409	$ 27	436
Other information			
Operating cash flows out from operating leases	(634)	(160)	(794)
Operating cash flows in from operating leases	215	133	348
Operating cash flows from financing leases	(35)	—	(35)
Right-of-use assets exchanged for new operating lease liabilities	874	—	874
Weighted average remaining lease term	1.4	1.8	
Weighted average discount rate—operating leases	8%	8%	

Maturities of the Company's operating leases, excluding short-term leases, are as follows:

(in thousands)	U.S.	Ireland	Total
Nine months ended December 31, 2019	$129	$ 51	$ 180
Year ended December 31, 2020	498	203	701
Year ended December 31, 2021	79	119	198
Total	706	373	1,079
Less present value discount	(40)	(27)	(67)
Operating lease liabilities included in the condensed consolidated balance sheets at September 30, 2019	$666	$ 346	$1,012

(8) OUTSTANDING DEBT

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 warrants to purchase 5,605 shares of the Company's common stock (the "Series D Warrants") and warrants to purchase 0.1 million shares of the Company's common stock (the "Pre-Funded Series D Warrants"). Under the terms of the Purchase Agreement, the Company agreed to sell and issue to the investors 8% Senior Secured Promissory Notes in an aggregate principal amount of $2.0 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants. This agreement was effective on July 15, 2019, upon the closing of the Company's Private Placement discussed further in Note 9. The principal is recognized in Convertible notes payable, long-term on the Condensed Consolidated Balance Sheet.

On April 19, 2019, April 26, 2019, May 9, 2019 and May 23, 2019, the Company issued 8% senior secured notes (collectively, the "2019 Notes") in the aggregate principal amount of $3.3 million, to two institutional investors. The 2019 Notes bore interest at the rate of 8% per annum and were to mature on the six-month anniversary of issuance in each case. The 2019 Notes were not convertible. The 2019 Notes contained standard events of default and remedies and are secured by a lien on the Company's assets. The 2019 Notes were exchanged as part of the recent equity financing discussed further in Note 9 and are no longer outstanding.

In March 2019, the Company exchanged all issued and outstanding shares of its Series D Preferred Stock (having an aggregate stated value of $1,160,000) and received $400,000 in cash proceeds in exchange for a senior secured promissory note (the "March 2019 Note") in the principal amount of $1,560,000. The March

2019 Note bore interest at the rate of 8% per annum, and were to mature on April 1, 2020, and was not convertible. The March 2019 Note was exchanged as part of the recent equity financing discussed further in Note 9 and is no longer outstanding.

On June 4, 2018, July 21, 2018, August 29, 2018, and September 21, 2018, the Company issued 8% senior secured convertible notes (collectively, the "2018 Notes") in the aggregate principal amount of $9.4 million to several institutional investors. The 2018 Notes bore interest at the rate of 8% per annum and had maturity dates between December 2018 and March 2021. The 2018 Notes were initially convertible and secured pursuant to a Security Agreement which created 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. In March 2019, the Company amended the June 2018, July 2018 and August 2018 Notes to make them non-convertible. There was no impact to the financial statements. In April 2019, the Company received notices of default from the investors in the 2018 Notes which resulted in a 25%, or $1.1 million, increase in principal and an increase in the interest rates from 8% to 18%. The 2018 Notes were exchanged as part of the recent equity financing discussed further in Note 9 and are no longer outstanding.

The following tables provide a summary of the various notes issued at September 30, 2019 and December 31, 2018:

(in millions)	Conversion price	Current interest rate	Principal
Long term convertible notes payable			
8.0% July 2019 Notes	$ 1,500	8%	$ 2.0

(in millions)	Interest rate	Conversion price	Principal	Unamortized discount	Carrying value
December 4, 2018	8.0%	$ 1,225	$ 1.7	$ —	$ 1.7
March 1, 2019	8.0%	$ 1,225	0.6	(0.5)	0.1
March 21, 2019	8.0%	$ 1,225	0.4	(0.2)	0.2
December 4, 2019	8.0%	$ 1,225	0.9	(0.9)	—
March 1, 2020	8.0%	$ 1,225	0.8	(0.8)	—
March 21, 2020	8.0%	$ 1,225	0.1	(0.1)	—
Balance at December 31, 2018			**$ 4.5**	**$ (2.5)**	**$ 2.0**

(9) STOCKHOLDERS' EQUITY

Preferred Stock Issuances

Series E and Series E-1 Preferred Stock

On July 11, 2019, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company sold to investors an aggregate of 20,000 shares of Series E convertible preferred stock, par value $0.01 per share (the "Series E Preferred Stock"), at a price of $1,000 per share and a warrant (a "2019 Warrant") to purchase a number of shares of common stock of the Company, equal to the number of shares of common stock issuable upon conversion of the Series E Preferred Stock purchased by the investor (the "July 2019 Private Placement"). The Company received gross proceeds from the July 2019 Private Placement of $20.0 million.

On August 19, 2019, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company sold to investors an aggregate of 9,510 shares of Series E-1 convertible preferred stock, par value $0.01 per share (the "Series E-1 Preferred Stock") at a price of $1,000 per share and a warrant (a "2019 Warrant") to purchase a number of shares of common stock of the Company equal to the number of shares of common stock issuable upon conversion of the Series E-1 stock

issuable upon conversion of the Series E-1 Preferred Stock purchased by the investor (the "August 2019 Private Placement"). The Company received gross proceeds from the August 2019 Private Placement of $9.5 million.

Each share of Series E Preferred Stock and Series E-1 Preferred Stock (collectively, the "Preferred Stock") is convertible at any time at the option of the holder into the number of shares of Common Stock determined by dividing the stated value by the conversion price of $25.36, subject to certain limitations and adjustments
(the "Conversion Price"). Except for certain adjustments, the holders of the Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an "as converted" basis) to and in the same form as dividends paid on shares of the Common Stock. Any such dividends that are not paid to the holders of the Preferred Stock will increase the stated value. No other dividends will be paid on shares of Preferred Stock. Each Warrant has an exercise price equal to $25.36, subject to adjustment in accordance with the terms of the Warrants (the "Exercise Price"), and are exercisable at any time beginning on the date that the Company effects a reverse stock split until 5:00 p.m. (NYC time) on the date that is five years following the date that the Company effects a reverse stock split.

The Conversion Price and the Exercise Price may, upon each of (i) the third trading day following the date that the Company effects a reverse stock split, (ii) the date that the initial registration statement to be filed pursuant to the Registration Rights Agreement (as further discussed below) is declared effective by the United States Securities and Exchange Commission (the "SEC"), and (iii) in the event that all of the registrable securities (as defined in the Registration Rights Agreement) are not then registered on an effective registration statement, the date that all of the shares underlying the Preferred Stock and Warrants may be sold pursuant to Rule 144, be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price or Exercise Price, as applicable, and (y) 90% of the average of the five daily volume weighted average prices of the Common Stock immediately prior to such dates. In the event of a reduction in the Exercise Price, the aggregate number of Warrant Shares shall be increased such that the aggregate Exercise Price of the Warrants on the day immediately following such reduction in the Exercise Price is equal to the aggregate Exercise Price immediately prior to such adjustment. In addition, from the date of issuance of the Preferred Stock and Warrants until such time that the Company's Common Stock is listed or quoted on a national exchange, the Conversion Price and the Exercise Price are subject to price-based anti-dilution protections.

The Company received net proceeds after expenses of $26.5 million. As discussed further in Note 8, the Company exchanged $11.8 million of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and related warrants. The Company also exchanged $0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related warrants and issued 923 shares of Series E Preferred Stock and related Warrants to certain investors in exchange for a waiver of rights under exchange agreements signed in December 2018 and March 2019. Of the net proceeds and equitized value received, the Company allocated an estimated fair value of $20.8 million to the 2019 Warrants. As a result of the Series E Preferred Stock and Series E-1 Preferred Stock having an effective conversion price that was lower than the market price on the date of issuance, the Company has recognized a beneficial conversion feature of $18.3 million. Due to the Series E Preferred Stock and Series E-1 Preferred Stock being immediately convertible, the beneficial conversion feature was recognized in full as a deemed dividend.

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. On March 29, 2019, the Company exchanged all issued and outstanding shares of its Series D Preferred Stock (having an aggregate stated value of $1,160,000) and received $400,000 in cash proceeds in exchange for the issuance of the March 2019 Notes. Please see the discussion under Note 8 above.

Common Stock Issuances

During the nine months ended September 30, 2019 the Company issued 11,285 shares of the Company's common stock pursuant to the exercise of Pre-Funded Series D Warrants that were issued in connection with the 2018 Notes discussed in Note 8 above.

Warrant Exchange

In April 2019, the Company entered into an exchange agreement with an institutional investor with respect to warrants held by such investor (the "February 2018 Warrants"). The February 2018 Warrants were issued to several institutional investors as part of the Company's February 2018 sale of the Company's common stock and the issuance of warrants to purchase common shares. Pursuant to the exchange agreement, the Company issued 92 shares of the Company's common stock (the "Exchange Shares") in exchange for the February 2018 Warrants. The exchange resulted in a loss of approximately $6,000 which is recognized in the statement of operations.

Share-Based Compensation

The Company's 2019 Equity Incentive Plan (the "Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares reserved for issuance under the Plan is 2,142. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant. As of September 30, 2019, the Plan had approximately 502 shares available for grant.

The following is a summary of stock option activity under the Plan for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	—			
Granted	1,782	196.70		
Exercised	—			
Cancelled/Forfeited	(142)	196.70		
Outstanding at September 30, 2019	1,640	$ 196.70	9.4	$ —
Exercisable at September 30, 2019	1,095	$ 196.70	9.4	$ —

The following weighted average assumptions were used to compute the fair value of stock options granted during the nine months ended September 30, 2019:

	Nine months ended September 30, 2019
Dividend yield	N/A
Expected volatility	147.6%
Weighted average risk-free interest rate	2.6%
Weighted average expected life (in years)	5.5
Weighted average grant date fair value	$ 0.259

At September 30, 2019, there was approximately $0.1 million of total unrecognized compensation expense related to non-vested share-based compensation awards under the plans for employee and board stock

option grants. The cost is expected to be recognized over a weighted average period of 0.3 years. For the three and nine months ended September 30, 2019, the Company recognized share-based compensation expense of approximately $70,000 and $203,000 in the statement of operations, respectively. For the same periods in 2018, the Company recognized share-based compensation expense of approximately $116,000 and income of $5,000 in the statement of operations, respectively.

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2019	2018	2019	2018
Selling, general and administrative	$ 54	$ 116	$ 160	$ 58
Research and development	16	—	43	(63)
Total	$ 70	$ 116	$ 203	$ (5)

Warrants

The following is a summary of warrant activity for the nine months ended September 30, 2019:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2018	93,835	$ 7.00 - $7,000	$ 150.67	5.75
Issued	1,001,995		42.00	
Exercised	(11,285)		7.00	
Exchanged	(82,521)		170.31	
Outstanding at September 30, 2019	1,002,024	$ 7.00 - $42.00	$ 42.00	5.05

(10) FAIR VALUE MEASUREMENTS

The table below presents the activity within Level 3 of the fair value hierarchy for the nine months ended September 30, 2019:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2018	$ 33
Total change in the liability included in earnings	(456)
Reclass from liability to equity	(11)
Fair value of warrants issued	20,844
Balance at September 30, 2019	$ 20,410

At September 30, 2019, the Company had a total of 125,000 February 2018 Warrants outstanding. As discussed in Part II—Item 1 "Legal Proceedings" and in Note 12 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, the February 2018 Warrants were surrendered pursuant to a settlement agreement entered into between the Company and the remaining holders of the February 2018 Warrants on April 18, 2019 and final payment under the settlement was made on July 16, 2019. The fair value of the outstanding warrants at September 30, 2019 and December 31, 2018 was determined by using option pricing models with the following assumptions:

	September 30, 2019	December 31, 2018
Expected life (in years)	5.0	1.1 - 5.1
Expected volatility	201.8%	145.7% - 265.3%
Risk-free interest rates	1.6%	2.5% - 2.6%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2019, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

(in thousands)	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Total	
	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
Liabilities								
Derivative instrument liabilities	$ —	$ —	$ —	$ —	$ 20,410	$ 33	$ 20,410	$ 33

For the periods ended September 30, 2019 and December 31, 2018, there were no transfers in or out of Level 1, 2 or 3 inputs.

(11) 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, without consideration of potentially dilutive securities except for those shares that are issuable for little or no cash consideration. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except share data)	**2019**	**2018**	**2019**	**2018**
Net (loss) income—basic	$ (7,519)	$ (8,880)	$ (21,371)	$ (8,353)
Preferred stock dividends	(18,238)	—	(18,238)	—
Adjustment for gain on warrant income	—	(13)	—	(534)
Net loss—diluted	$(25,757)	$ (8,893)	$ (39,609)	$ (8,887)
Weighted average shares outstanding—basic*	26,112	51,229	23,095	19,841
Weighted average shares outstanding—diluted*	26,112	51,229	23,095	19,841
Net loss per share—basic*	$(287.00)	$(175.00)	$ (924.00)	$(420.00)
Net loss per share—diluted*	$(987.00)	$(175.00)	$(1,715.00)	$(448.00)

* reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018 and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

As discussed in Note 9, the Series E Preferred Stock and the Series E-1 Preferred Stock were each determined to have a beneficial conversion feature which was accounted for as a deemed dividend.

The following potentially dilutive securities were excluded from the computation of earnings per share as of September 30, 2019 and 2018 because their effects would be anti-dilutive:

	September 30,	
	2019	**2018**
Stock options	1,643	—
Common stock warrants—equity	—	6,005
Common stock warrants—liability	1,001,963	1,429
Assumed conversion of Series E and E-1 Preferred Stock	1,001,963	—
Assumed conversion of convertible notes	31,747	8,057
Total	2,037,316	15,491

(12) TAXES

As discussed in Note 14 *Income Taxes* to the Consolidated Financial Statements included in the Company's Annual Report filed for the fiscal year ended December 31, 2018, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. 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. Additional information regarding the statutes of limitations can be found in Note 14 *Income Taxes* to the Consolidated Financial Statements included in the Company's Annual Report filed for the fiscal year ended December 31, 2018.

(13) COMMITMENT AND CONTINGENCIES

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.

(14) SUBSEQUENT EVENTS

Amendments to Registration Rights Agreements

On September 30, 2019, the Company and holders of a majority of the Company's Series E and Series E-1 Convertible Preferred Stock entered into an amendment to those certain registration rights agreements, dated as of July 11, 2019 (effective as of July 15, 2019) (the "July Registration Rights Agreement"), and August 15, 2019 (the "August Registration Rights Agreement") between the Company and the holders signatory thereto (the "Amendment"). The Amendment extends the applicable deadline for having a registration statement declared effective by the Securities and Exchange Commission (the "SEC") under certain circumstances from 75 days to 120 days following the date of the July Registration Rights Agreement.

On October 18, 2019, the Company and holders of a majority of the Company's Series E and Series E-1 Convertible Preferred Stock entered into a second amendment (the "Second Amendment") to those certain registration rights agreements, dated as of July 11, 2019 (effective as of July 15, 2019) and August 15, 2019, in each case as amended on September 30, 2019, between the Company and the holders signatory thereto. The Second Amendment eliminates the deadline to file a pre-effective registration statement amendment within 10 days of the Company's receipt of comments from the SEC.

On October 29, 2019, the Company and holders of a majority of the Company's Series E and Series E-1 Convertible Preferred Stock and related warrants entered into a third amendment (the "Third Amendment") to those certain registration rights agreements, dated as of July 11, 2019 (effective as of July 15, 2019) and August 15, 2019, in each case as previously amended on September 30, 2019 and October 18, 2019, between the Company and the holders signatory thereto (collectively, the "Registration Rights Agreements"). The Third Amendment clarifies that the liquidated damages specified in Section 2(d) of the Registration Rights Agreements shall not be payable to any holder whose Registrable Securities, as defined in the Registration Rights Agreements, are fully registered on an effective registration statement on the Effectiveness Date, as defined in the Registration Rights Agreements.

Waiver and Forbearance Agreement

Also on October 29, 2019, the Company entered into a Waiver and Forbearance Agreement ("Waiver") with Rosalind Master Fund LP and Rosalind Opportunities Fund I LP, holders of its Series E and Series E-1 Convertible Preferred Stock and related warrants (together, "Rosalind") pursuant to which Rosalind has agreed, among other things, to waive compliance with certain specified terms and conditions under the Registration Rights Agreements and forbear from exercising certain of their rights and remedies related to certain defaults thereunder for the time periods indicated therein.

Reverse Stock Split

Pursuant to the Company's obligations under the July 2019 Private Placement and the August 2019 Private Placement, the Company presented a proposal for a reverse stock split at its Annual Meeting of Stockholders on September 17, 2019. On the same date, a majority of stockholders of the Company approved a proposal to approve and adopt an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our shares of common stock, $0.01 par value per share, issued and outstanding or reserved for issuance, at a specific ratio within a range from 1-for-50 to 1-for-1,200, inclusive, prior to the first anniversary of stockholder approval of the proposal, and to grant authorization to the Board of Directors to determine, in its sole discretion, whether to effect the reverse stock split, as well as its specific timing and ratio. Also on the same date, the Company's Board of Directors adopted resolutions to effect as soon as reasonably practicable the reverse split of the issued and outstanding shares of the Common Stock at a ratio of 1-for-100.

On October 17, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation (the "Charter Amendment") to effect a reverse stock split of the issued and outstanding shares of the Company's common stock, $0.01 par value per share, at a ratio of 1-for-100 to be effective as of October 22, 2019 at 8:30 a.m., New York City time (the "Reverse Stock Split"). The Charter Amendment did not change the par value or any other terms of the common stock.

On October 22, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Correction (the "Certificate of Correction") to the Charter Amendment, rescinding the Charter Amendment, citing an inaccuracy in Article Third of the Charter Amendment, which states an effective time for the Reverse Stock Split of 8:30 a.m. New York City time on October 22, 2019. Such effective time was based upon the Company's prior receipt, on October 17, 2019, of confirmation by the Financial Industry Regulatory Authority, Inc. ("FINRA") that it had completed its review of the Reverse Stock Split, including the effective time, whereupon the Company undertook to effect the Reverse Stock Split by filing the Charter Amendment. On the evening of October 21, 2019, subsequent to the Company's filing of the Charter Amendment and issuance of a press release on October 18, 2019 announcing the confirmation by FINRA, FINRA notified the Company's counsel that it was rescinding its prior confirmation. The Certificate of Correction further provides that the Company is currently awaiting FINRA confirmation. When such confirmation is obtained, the Company intends to file a Certificate of Amendment effectuating the Reverse Stock Split.

Following FINRA's completion of its review of the Company's Reverse Stock Split, on December 24, 2019, the Company effected a reverse stock split at which time Delcath's common stock began trading on the OTCQB on a one-for-seven hundred (1:700) split-adjusted basis. All owners of record as of the open of the OTCQB market on December 24, 2019 received one issued and outstanding share of Delcath common stock in exchange for seven hundred outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-seven hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company's consolidated financial statements and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

Preferred Stock conversions

From October 1, 2019 through November 14, 2019, the Company issued 5,286 shares of Common Stock to the holders of Series E and Series E-1 Preferred Stock pursuant to conversion notices submitted by the holders.

1,470,588 Shares of Common Stock

PROSPECTUS

Sole Book-Running Manager

Roth Capital Partners

Co-Manager

Aegis Capital Corp.

The date of this prospectus is , 2020