Filed Pursuant to Rule 424(b)(5)
Registration No. 333-227970

PROSPECTUS SUPPLEMENT
(To Prospectus dated December 21, 2018)

Up to $10,000,000

Common Stock

We have entered into a Controlled Equity Offering℠ Sales Agreement, or sales agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, relating to shares of our common stock, $0.01 par value per share, offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the sales agreement, from time to time we may offer and sell shares of our common stock having an aggregate gross sales price of up to $10.0 million through Cantor Fitzgerald, acting as sales agent, pursuant to this prospectus supplement and the accompanying prospectus.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "DCTH." On August 14, 2020, the last reported sale price of our Common Stock on The Nasdaq Capital Market was $12.43 per share.

Sales of our Common Stock, if any, under this prospectus supplement may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or the Securities Act. Subject to terms of the sales agreement, Cantor Fitzgerald is not required to sell any specific number or dollar amounts of securities but will act as our sales agent using commercially reasonable best efforts consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald will be entitled to compensation under the terms of the sales agreement at a fixed commission rate of 3.0% of the gross sales price per share sold. In connection with the sale of our Common Stock on our behalf, Cantor Fitzgerald will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contributions to Cantor Fitzgerald against certain civil liabilities, including liabilities under the Securities Act. See "Plan of Distribution" beginning on page S-48 of this prospectus supplement for more information regarding our arrangements with the Sales Agent.

As of August 14, 2020, the aggregate market value of our outstanding Common Stock held by non-affiliates was approximately $47.3 million based on 3,807,755 shares of Common Stock held by non-affiliates and the last reported sale price of our Common Stock on such date. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell shares registered on the registration statement of which this prospectus supplement is a part with a value of more than one-third of the aggregate market value of our Common Stock held by non-affiliates in any 12-month period, so long as the aggregate market value of our Common Stock held by non-affiliates remains below $75.0 million. During the 12 calendar months prior to, and including, the date of this prospectus supplement, we have not sold any securities pursuant to General Instruction I.B.6 of Form S-3.

Investing in our Common Stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" on page S-8 of this prospectus supplement, and under similar headings in the documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement and the accompanying prospectus are truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is August 18, 2020.

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Prospectus Supplement

Prospectus

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 and the amendments thereto that we filed with the Securities and Exchange Commission, or the "SEC", using a "shelf" registration process relating to the Common Stock described in this prospectus supplement, which registration statement was declared effective on December 21, 2018. Before buying any of the Common Stock that we are offering, we urge you to carefully read this entire prospectus supplement and the accompanying prospectus, together with the documents incorporated by reference that are described under the headings "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference" on pages S-49 and S-50 of this prospectus supplement. These documents contain important information that you should consider when making your investment decision.

Unless otherwise specified or required by context, references in this prospectus supplement to the "Company," "we," "us" and "our" refer to Delcath Systems, Inc., a Delaware corporation.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of the Offering and also adds to, updates and changes information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the Company and the securities that we may offer from time to time under our shelf registration statement, some of which may not apply to the Common Stock offered by this prospectus supplement. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent the information contained in this prospectus supplement differs from or conflicts with the information contained in the accompanying prospectus or any document incorporated by reference into the accompanying prospectus, the information in this prospectus supplement will control. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus supplement and the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We have not, and the Sales Agent has not, authorized anyone to provide you with information different from that which is contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we may authorize for use in connection with this Offering. No one is making offers to sell or seeking offers to buy our Common Stock in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus supplement is accurate as of the date on the front cover of this prospectus supplement only and that any information we have incorporated by reference or included in the accompanying prospectus is accurate only as of the date given in the document incorporated by reference or as of the date of the prospectus, as applicable, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus, any related free writing prospectus, or any sale of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference may include trademarks, service marks and trade names owned or licensed by us, including CHEMOFUSE, CHEMOSAT, CHEMOSATURATION, DELCATH, ISO-FUSE, PHP and THE DELCATH PHP SYSTEM. Solely for convenience, trademarks and trade names, including logos, artwork and other visual

displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of the Company or the Company's licensor, as applicable.

Information contained on, or that can be accessed through, our website does not constitute part of this prospectus supplement, the accompanying prospectus or any related free writing prospectus.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us and this Offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our Common Stock. For a more complete understanding of the Company and this Offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we authorize for use in connection with this Offering, including the information contained in and incorporated by reference under the heading "Risk Factors" beginning on page S-9 of this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement and the accompanying prospectus.

Our Business

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 CHEMOSAT ® Hepatic 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. We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. 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 (one for doxorubicin in hepatocellular indication and five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma and neuroendocrine tumor indications), 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 presently 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 certain primary liver cancers and 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. According to Lane et al, once ocular melanoma has spread to the liver, median overall survival for these patients is generally 1.7 months (untreated) to 6.3 months (treated).(1) There is no one standard of care for patients with ocular melanoma liver metastases.

As per the American Society for Clinical Oncology, it is estimated that approximately 3,400 cases of ocular melanoma are diagnosed in the United States annually.(2) According to the Ocular Melanoma Foundation, approximately 50% of these patients will develop metastatic disease; of metastatic cases of ocular melanoma, approximately 90% of patients will develop liver involvement.(3) We estimate that approximately 1,530 patients with ocular melanoma liver metastases in the United States could be candidates for treatment with Melphalan/HDS annually. We estimate the annual addressable market for this indication in the United States is over $250 million per year.

Intrahepatic Cholangiocarcinoma

ICC is the second most common form of primary liver cancer.(4)

ICC is frequently a “clinically silent” disease, resulting in a high proportion of patients presenting with advanced disease where surgical resection is no longer feasible.(5) According to the American Cancer Society (ACS), the overall five-year survival rate for ICC in the United States is approximately 8%. For patients diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 24%.(6)

According to Patel et al, the annual incidence of ICC in the United States is 0.90 per 100,000 persons.[5] Based on the current US population, we therefore estimate that approximately 2960 ICC patients in the United States could be candidates for treatment with Melphalan/HDS annually. We estimate the annual addressable market for this indication in the United States is over $450 million per year.

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 adsorb 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.

References

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3. Ocular Melanoma Foundation. Treatment of Metastatic Disease. In: OMF - Metastatic Treatment. http://www.ocularmelanoma.org/metstreatment.htm. Accessed 22 Jun 2020
4. Wang Y, Li J, Xia Y, Gong R, Wang K, Yan Z, Wan X, Liu G, Wu D, Shi L, Lau W, Wu M, Shen F. Prognostic nomogram for intrahepatic cholangiocarcinoma after partial hepatectomy. *J Clin Oncol*. 2013;31(9):1188-1195. doi:10.1200/JCO.2012.41.5984
5. Patel N, Benipal B. Incidence of Cholangiocarcinoma in the USA from 2001 to 2015: A US Cancer Statistics Analysis of 50 States. *Cureus*. 2019;11(1):e3962. Published 2019 Jan 25.
6. American Cancer Society. Bile Duct Cancer Early Detection, Diagnosis, and Staging. Cancer.org. Published 2018 Jul 3. https://www.cancer.org/content/dam/CRC/PDF/Public/8554.00.pdf Accessed 6 Jul 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 supplement.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

THE OFFERING

Common stock offered by us	Shares of our common stock, par value $0.01 per share, with an aggregate sale price of up to $10,000,000.
Common Stock outstanding immediately after this offering	Up to 4,819,673 shares of our Common Stock, assuming sales of 804,505 shares of our common stock in this offering at an assumed offering price of $12.43 per share, which was the last reported sale price of our Common Stock on the Nasdaq Capital Market on August 14, 2020. The actual number of shares issued will vary depending on the sales prices at which our common stock is sold under this offering.
Plan of Distribution	"At the market offering" that may be made from time to time through our sales agent, Cantor Fitzgerald. See "Plan of Distribution" on page S-48 of this prospectus supplement.
Use of Proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes, which may include capital expenditures, debt repayment, and research and development, sales and marketing and general and administrative expenses. See "Use of Proceeds" on page S-44 of this prospectus supplement.
Risk Factors	Investing in our Common Stock involves a high degree of risk. See the information contained in or incorporated by reference under the heading "Risk Factors" on page S-9 of this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and any free writing prospectus that we authorize for use in connection with this offering.
Nasdaq Capital Market symbol	DCTH

The number of shares of our Common Stock to be outstanding after this Offering is based on 3,521,641 shares of our Common Stock outstanding as of June 30, 2020, and excludes the following:

- 2,595,087 shares of Common Stock reserved for issuance pursuant to the conversion of 25,951 shares of preferred stock, based on the $10.00 conversion price in effect as of June 30, 2020.
- 4,051,499 shares of our Common Stock reserved for issuance upon exercise of outstanding warrants having a weighted average exercise price of $10.00 per share at June 30, 2020;
- 371,000 shares of Common Stock reserved for issuance upon exercise of the pre-funded warrants issued in connection with the May 2020 public offering;
- 1,640 shares of our Common Stock reserved for issuance upon exercise of outstanding options having a weighted average exercise price of $196.70 per share; and
- 146,288 shares of our Common Stock underlying the assumed conversion of convertible notes based on the conversion price in effect as of June 30, 2020.

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully review the risks and uncertainties described below and discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as updated by our most recent quarterly reports on Form 10-Q, which are filed with the SEC and incorporated by reference into this prospectus supplement, before deciding whether to purchase any Common Stock in this Offering. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our Common Stock, and the occurrence of any of these risks might cause you to lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Please also read carefully the section below entitled "Cautionary Note Concerning Forward-Looking Statements."

Risks Related to the COVID-19 Pandemic

The "Novel Coronavirus Disease 2019" ("COVID-19") pandemic has materially and adversely affected our clinical trial operations and may materially and adversely affect our financial results.

The COVID-19 pandemic has affected many countries, including the United States and several European countries, where we are currently conducting our FOCUS Trial and ALIGN Trial. In response to the pandemic, hospitals participating in the trials in affected countries have taken a number of actions, including restricting elective and other procedures that are not deemed to be life-threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials have had the start of their treatments postponed and ongoing treatment regimens may be delayed. In addition, we do not have sufficient access to monitor trial data on a timely basis. These restrictions have had a materially adverse effect on our clinical operations. We expected to announce top-line data from our FOCUS trial in mid-2020. We will not be able to release the top-line data from the FOCUS Trial within the timeframe we had anticipated. Once our clinical trial sites are able to return to normal operating procedures, we will assess the impact and update our expected timing accordingly.

The extent to which the COVID-19 pandemic may affect our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the spread and severity of COVID-19, and the effectiveness of governmental actions in response to the pandemic. Furthermore, the spread of COVID-19 may materially and adversely affect our ability to recruit and retain patients.

We expect that actions taken in response to the COVID-19 pandemic will also materially and adversely affect sales of CHEMOSAT. As noted above, some hospitals are restricting procedures that are not deemed to be life-threatening at this time. Because CHEMOSAT is not deemed to be an essential procedure, we expect that the number of procedures performed could decline. While we do not expect revenues from CHEMOSAT procedures to be material to us, a decrease in the number of procedures performed would adversely affect our expected revenues and our financial results.

These consequences of the COVID-19 pandemic will delay and could adversely affect our ability to obtain regulatory approval for and to commercialize our products, increase our operating expenses, and could have a material adverse effect on our financial results. The situation continues to rapidly change and additional impacts to our business may arise that we are not aware of currently. The ultimate impact of the pandemic on the Company's results of operations, financial position, liquidity or capital resources cannot be reasonably estimated at this time.

Additional Risks Related to This Offering

We have broad discretion in how we use the net proceeds from this Offering, and we may not use these proceeds effectively or in ways with which you agree.

We have not designated any portion of the net proceeds from this Offering to be used for any particular purpose. Our management will have broad discretion as to the application of the net proceeds from this Offering and could use them for purposes other than those contemplated at the time of this Offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase the market price of our Common Stock.

You may experience immediate and substantial dilution.

The offering price per share of Common Stock in this offering may exceed the net tangible book value per share of our Common Stock outstanding prior to this Offering. Assuming that an aggregate of 804,505 shares of our Common Stock are sold at a price of $12.43 per share pursuant to this prospectus supplement, which was the last reported sale price of our common stock on the Nasdaq Capital Market on August 14, 2020, for aggregate gross proceeds of $10.0 million, after deducting commissions and estimated aggregate offering expenses payable by us, you would experience immediate dilution of $8.48 per share, representing the difference between our as adjusted net tangible book value per share as of December 31, 2019 after giving effect to this Offering and the assumed offering price. The conversion of preferred stock and the exercise of outstanding stock options and warrants may result in further dilution of your investment. See “Dilution” in this prospectus supplement for a more detailed illustration of the dilution you would incur if you participate in this Offering.

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

In order to raise additional capital, we may in the future 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 price per share paid by any investors 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 price per share paid by any investors in this Offering.

We do not intend to pay dividends in the foreseeable future.

We have never declared or paid any cash dividend on our Common Stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, 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.

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 as of December 31, 2019.

Our independent registered public accounting firm issued a report dated March 25, 2020 in connection with the audit of our financial statements as of December 31, 2019, 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, 2019, included in our Annual Report on Form 10-K filed with the SEC on March 25, 2020, 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 may not generate material 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 June 30, 2020, we had $16.0 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, 2019 and 2018, we incurred net losses of approximately $8.9 million and $19.2 million, respectively and expect to continue to incur losses in 2020. 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. 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;
- executive compensation, including the cost of attracting and retaining a permanent CEO and CFO and resolving potential disputes with the former CEO and CFO;
- 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 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. 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 develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic 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 presently 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 conduct 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 typical 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, FDA 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 could 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. 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 us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, FDA 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 with a prior version of the medical device and procedure in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of that same version of the 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, commercialization of CHEMOSAT in the EU may not be successful.

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 became more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) came 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 conduct finishing operations, assembly, packaging/labeling/distribution at this facility in Galway, Ireland. We currently utilize third-parties to manufacture some components of CHEMOSAT and Melphalan/HDS.

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.

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. Pursuant to the worldwide coronavirus pandemic, on 17 April 2020, the European Parliament adopted the European Commission’s proposal to postpone the implementation of the MDR (EU) 2017/745 by 12 months. This urgently drafted proposal to delay the MDR is in response to the exceptional circumstances associated with the COVID-19 pandemic and the potential impact it may have had on the MDR implementation. The new Date of Application (DoA) for the MDR will be 26 May 2021.

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.

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

While we have written contracts and supply agreements for key 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. Following the recent resignations of our former chief executive officer and

chief financial officer, those positions are currently being filled on an interim basis by other Company executives, and we intend to perform a search process to locate persons to permanently fill those positions. 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.

Any current or future outbreak of a health epidemic or other adverse public health developments, such as the current outbreak of COVID-19, could disrupt our manufacturing and supply chain, and adversely affect our business and operating results.

Our business could be adversely affected by the effects of health epidemics, specifically COVID-19. For example, our materials suppliers could be disrupted by conditions related to COVID-19, or other epidemics, possibly resulting in disruption to our supply chain. If our suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. At this point in time, there is uncertainty relating to the potential effect of COVID-19 on our business. Infections may become more widespread and should that limit our ability to manufacture our products or cause supply disruptions it would have a negative impact on our business, financial condition and operating results. In addition, a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect the market for our products, which could have a material adverse effect on our business, operating results and financial condition.

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 products and technologies in 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 (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.

Our patent protection for CHEMOSAT and Melphalan/HDS is primarily in the United States and the EU, with additional design protection in Argentina, Australia, Canada, and China. We currently have patents in the United States and the EU directed to our product, system, procedure, and method of treatment. Our patents provide patent protection for our CHEMOSAT hepatic delivery system, hemofiltration cartridge apparatus, hemofiltration cartridge design, methods of treatment of a subject with cancer in accordance with various embodiments of our system, embodiments of our system for delivering a high concentration of a small molecule chemotherapeutic agent to a subject while minimizing systemic exposure to the small molecule chemotherapeutic agent, and methods of setting up a filter apparatus for hemofiltration in accordance with our procedures using our proprietary hepatic deliver system. However, patents have a limited lifespan. In the United States and the EU, the ordinary statutory natural expiration of a utility patent typically is generally 20 years from its filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

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, or misappropriate, 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, offer for sale, 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 for our customers our products 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. 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 in countries where we do not have patent protection.

Similar considerations apply in foreign countries where we receive approval and 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 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.

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.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents we have filed with the Securities and Exchange Commission, or SEC, that are incorporated by reference herein 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 S-10.

- 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 Delcath Hepatic Delivery 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 S-10 and in reports we will file from time to time with the SEC after the date of this prospectus supplement.

USE OF PROCEEDS

We may issue and sell shares of our Common Stock in this Offering having aggregate sales proceeds of up to $10.0 million. Because there is no minimum offering amount required as a condition to close this Offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. There can be no assurance that we will sell any shares of our Common Stock under or fully utilize the sales agreement with Cantor Fitzgerald as a source of financing.

We estimate that the net proceeds from this Offering will be approximately $9.4 million, after deducting the Sales Agent's fees and the estimated expenses payable by us in connection with this Offering, including a fee equal to 1.05% of the gross sales price per share sold in this Offering pursuant to the terms of a limited waiver between the Company and ROTH Capital Partners, LLC.

We intend to use the net proceeds from this Offering for working capital and general corporate purposes, which may include capital expenditures, debt repayment, and research and development, sales and marketing and general and administrative expenses. We may also use a portion of the net proceeds from this offering to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any such acquisitions or investments as of the date of this prospectus supplement. We will retain broad discretion over the use of the net proceeds from this Offering.

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 price per share you pay in this Offering and the net tangible book value per share of our Common Stock immediately after this Offering.

Our net tangible book value as of June 30, 2020 was approximately $7.7 million, or $2.19 per share. We calculate net tangible book value per share by dividing the net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our Common Stock. Dilution represents the difference between the portion of the amount per share paid by purchasers of shares in this Offering and the as adjusted net tangible book value per share of our Common Stock immediately after giving effect to this Offering.

After giving effect to the assumed sale by us of 804,505 shares of our Common Stock in the aggregate amount of $10.0 million in this Offering at an assumed offering price of $12.43 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on August 14, 2020 and after deducting commissions and estimated aggregate offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2020 would have been approximately $17.1 million, or $3.95 per share of common stock. This represents an immediate increase in net tangible book value per share of $1.76 to our existing stockholders and an immediate dilution in net tangible book value per share of $8.48 to new investors purchasing Common Stock in this Offering. The following table illustrates this dilution on a per share basis to new investors participating in this Offering.

Assumed offering price per share		$12.43
Net tangible book value per share as of June 30, 2020	$2.19	
Increase in net tangible book value per share of common stock attributable to investors purchasing our common stock in this offering	$1.76	
Adjusted net tangible book value per share of common stock immediately after this offering		$ 3.95
Dilution per share to new investors in this offering		$ 8.48

The table above assumes, for illustrative purposes, that an aggregate of 804,505 shares of our Common Stock are sold at a price of $12.43 per share, the last reported sale price of our common stock on the Nasdaq Capital Market on August 14, 2020, for aggregate gross proceeds of $10.0 million. The shares sold in this Offering, if any, will be sold from time to time at various prices. An increase of $1.00 per share in the price at which the shares are sold from the assumed offering price of $12.43 per share shown in the table above, assuming all of our Common Stock in the aggregate amount of $10.0 million during the term of the sales agreement with Cantor Fitzgerald is sold at that price, would increase our as adjusted net tangible book value per share after the offering to $4.01 per share and would increase the dilution in net tangible book value per share to new investors to $9.42 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of $1.00 per share in the price at which the shares are sold from the assumed offering price of $12.43 per share shown in the table above, assuming all of our Common Stock in the aggregate amount of $10.0 million during the term of the sales agreement with Cantor Fitzgerald is sold at that price, would decrease our as adjusted net tangible book value per share after the Offering to $3.89 per share and would decrease the dilution in net tangible book value per share to new investors to $7.54 per share, after deducting commissions and estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only and may differ based on the actual offering price and the actual number of shares offered.

The above discussion and table are based on 3,521,641 shares of our common stock outstanding as of June 30, 2020, and exclude:

- 1,640 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2020, at a weighted average exercise price of $196.70 per share;
- 4,051,499 shares of our Common Stock reserved for issuance upon exercise of outstanding warrants having a weighted average exercise price of $10.00 per share at June 30, 2020;
- 371,000 shares of Common Stock reserved for issuance upon exercise of the pre-funded warrants issued in connection with the May 2020 public offering;
- 2,595,087 shares of Common Stock reserved for issuance pursuant to the conversion of 25,951 shares of preferred stock, based on the $10.00 conversion price in effect as of June 30, 2020.
- 146,288 shares of our Common Stock underlying the assumed conversion of convertible notes.

To the extent that preferred stock has been converted or options or warrants outstanding as of June 30, 2020 have been or are exercised, investors purchasing shares in this Offering could experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or equity-based securities, the issuance of these securities could result in further dilution to our stockholders.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and do not currently anticipate paying cash dividends in the foreseeable future.

PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which we may offer and sell shares of our common stock. Pursuant to this prospectus supplement, we may offer and sell shares of our common stock having an aggregate gross sales price of up to $10,000,000 from time to time through Cantor Fitzgerald acting as agent. The Sales Agreement will be filed as an exhibit to a Current Report on Form 8-K.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald may offer and sell shares of our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. We may instruct Cantor Fitzgerald not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor Fitzgerald may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor Fitzgerald commissions, in cash, for its services in acting as agent in the sale of our common stock. Cantor Fitzgerald is entitled to compensation at a commission rate of 3.0% of the gross sales price per share sold under the Sales Agreement. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Cantor Fitzgerald for certain specified expenses, including the reasonable and documented fees and disbursements of its legal counsel in an amount not to exceed $50,000. We estimate that the total expenses for the offering under this prospectus supplement, excluding compensation and reimbursements payable to Cantor Fitzgerald under the terms of the Sales Agreement, will be approximately $160,500.

In addition, we will pay a fee equal to 1.05% of the gross sales price per share sold in this Offering pursuant to the terms of a limited waiver between the Company and ROTH Capital Partners, LLC.

Settlement for sales of shares of common stock will occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor Fitzgerald in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus supplement will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor Fitzgerald may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor Fitzgerald will use its commercially reasonable efforts, consistent with its sales and trading practices, to solicit offers to purchase the shares of common stock under the terms and subject to the conditions set forth in the Sales Agreement. In connection with the sale of the shares of common stock on our behalf, Cantor Fitzgerald will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor Fitzgerald (and its partners, members, directors, officers, employees and agents) against certain civil liabilities, including liabilities under the Securities Act.

The offering of shares of our common stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. We and Cantor Fitzgerald may each terminate the Sales Agreement at any time upon ten days' prior notice.

Cantor Fitzgerald and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us, our subsidiaries and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor Fitzgerald will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus supplement.

This prospectus supplement and the accompanying prospectus in electronic format may be made available on a website maintained by Cantor Fitzgerald and Cantor Fitzgerald may distribute this prospectus supplement and the accompanying prospectus electronically.

LEGAL MATTERS

The validity of the issuance of the Common Stock offered by this prospectus supplement will be passed upon for us by McCarter & English, LLP, Newark, New Jersey. Cantor Fitzgerald & Co. is being represented in connection with this Offering by Cooley LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2019 and 2018 and for the years then ended incorporated by reference in this prospectus supplement, have been so incorporated 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 our ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the shares of Common Stock we are offering under this prospectus supplement utilizing a shelf registration process, which registration statement was declared effective on December 21, 2018. This prospectus supplement and the accompanying prospectus do not contain all of the information set forth in the registration statement and the amendments and exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus supplement, we refer you to the registration statement and the amendments and thereto, and the exhibits and schedules filed as a part of the registration statement. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us. The SEC's Internet site can be found at www.sec.gov.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered part of this prospectus supplement and the accompanying prospectus. Later information filed with the SEC will update and supersede this information. The SEC's Internet site can be found at www.sec.gov.

We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement until the termination of the offering of the shares covered by this prospectus supplement (other than Current Reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items):

- our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 25, 2020;
- our quarterly reports on Form 10-Q for the periods ended March 31, 2020, filed with the SEC on May 14, 2020 and June 30, 2020, filed with the SEC on August 13, 2020;
- our Current Reports on Form 8-K, filed with the SEC on January 9, 2020, February 19, 2020, February 24, 2020, February 28, 2020, March 16, 2020, April 9, 2020, May 8, 2020, May 12, 2020, May 22, 2020, June 5, 2020, June 16, 2020 and July 21, 2020; and

- the description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on April 30, 2020, including any amendments or reports filed for the purpose of updating such description.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

Delcath Systems, Inc.
1633 Broadway, Suite 22C
New York, New York 10019
Attn: Christine Padula, Corporate Secretary
E-Mail: investorrelations@delcath.com
Telephone: (212) 489-2100

In accordance with Rule 412 of the Securities Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

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PROSPECTUS

$100,000,000

Common Stock
Preferred Stock
Senior Debt Securities
Depositary Shares
Warrants
Units

We may offer and sell up to $100,000,000 in the aggregate of the securities identified above from time to time in one or more offerings. This prospectus provides you with a general description of the securities.

Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. The supplement may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus entitled “About this Prospectus” and “Plan of Distribution” for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE THE “RISK FACTORS” ON PAGE 7 OF THIS PROSPECTUS AND ANY SIMILAR SECTION CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT CONCERNING FACTORS YOU SHOULD CONSIDER BEFORE INVESTING IN OUR SECURITIES.

Our common stock trades on the OTCQB under the symbol “DCTH”. The closing sale price on the OTCQB on December 12, 2018, was $0.36 per share.

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

The date of this prospectus is December 21, 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a "shelf" registration process. By using a shelf registration statement, we may sell securities from time to time and in one or more offerings up to a total dollar amount of $100,000,000 as described in this prospectus. Each time that we offer and sell securities, we will provide a prospectus supplement to this prospectus that contains specific information about the securities being offered and sold and the specific terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement or free writing prospectus may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement or free writing prospectus, you should rely on the prospectus supplement or free writing prospectus, as applicable. Before purchasing any securities, you should carefully read both this prospectus and the applicable prospectus supplement (and any applicable free writing prospectuses), together with the additional information described under the heading "Where You Can Find More Information; Incorporation by Reference."

We have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and the applicable prospectus supplement to this prospectus is accurate only as of the date on its respective cover, that the information appearing in any applicable free writing prospectus is accurate only as of the date of that free writing prospectus, and that any information incorporated by reference is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus incorporates by reference, and any prospectus supplement or free writing prospectus may contain and incorporate by reference, market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included or incorporated by reference in this prospectus, any prospectus supplement or any applicable free writing prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" contained in this prospectus, the applicable prospectus supplement and any applicable free writing prospectus, and under similar headings in other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

When we refer to "Delcath," "we," "our," "us" and the "Company" in this prospectus, we mean Delcath Systems, Inc., and its consolidated subsidiaries, unless otherwise specified. When we refer to "you," we mean the potential holders of the applicable series of securities.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Available Information

Our web site address is http://www.delcath.com/. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be

obtained from us, as provided below. Forms of the indenture and other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement or documents incorporated by reference in the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters.

Incorporation by Reference

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus and any accompanying prospectus supplement incorporate by reference the documents set forth below that have previously been filed with the SEC:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 16, 2018 and our Amendment No. 1 to Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on April 30, 2018 (amended to include "Part III" information);
- Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018, filed with the SEC on May 10, 2018, our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, filed with the SEC on August 14, 2018, and our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, filed with the SEC on November 13, 2018;
- Our Current Reports on Form 8-K filed with the SEC on January 26, 2018, February 12, 2018, March 13 and 26, 2018, April 9 and 26, 2018, June 8, 2018, July 26 and 30, 2018, September 7, 10 (8-K/A), 24, 27 and 28, 2018, October 17 and 24, 2018 and November 7, 2018; and
- A description of our common stock contained in our Current Report on Form 8-K filed with the SEC on December 12, 2018.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, which we refer to as the "Exchange Act" in this prospectus, prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

DELCATH SYSTEMS, INC.
Attn: Corporate Secretary
1633 Broadway, Suite 22C
New York, New York 10019
(212) 489-2100

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus or any accompanying prospectus supplement.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus, any applicable prospectus supplement or documents incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities.

We file reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information filed by us at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at (800) SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Delcath Systems, Inc. The address of the SEC website is http://www.sec.gov.

THE COMPANY

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

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

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. Although the Melphalan/HDS Kit has not been approved in the U.S., FDA has granted us six orphan drug designations, which apply to the orphan indication for the drug component even though approved as a drug/device, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma (HCC) and ICC. Melphalan/HDS has not been approved for sale in the United States. There are also orphan drug designations for melphalan for neurodendocrine tumors, cutaneous melanoma, and ocular tumors, as well as for the use of doxorubicin for HCC.

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

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 Phase 3 clinical trial that is investigating objective response rate in mOM, and The ALIGN Trial, a registration trial for intrahepatic cholangiocarcinoma (ICC). Our CDP also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs).

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

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

Cancers in the Liver—A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to the American Cancer Society's (ACS) *Cancer Facts & Figures 2017* report, cancer is the second leading cause of death in the United States,

with an estimated 600,920 deaths and 1,688,780 new cases expected to be diagnosed in 2017. Cancer is one of the leading causes of death worldwide, accounting for approximately 8.2 million deaths and 14.1 million new cases in 2012 according to GLOBOCAN. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the U.S. in 2014 was $87.8 billion. The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death. Patient prognosis is generally poor once cancer has spread to the liver.

Liver Cancers—Incidence and Mortality

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

Ocular Melanoma

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Based on third party research conducted in 2016, we estimate that up to 4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, we estimate that approximately 90% of patients will develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care (SOC) for patients with ocular melanoma liver metastases. According to our 2016 research, we estimate that approximately 2,000 patients with ocular melanoma liver metastases in the United States and Europe may be eligible for treatment with the Melphalan/HDS.

Intrahepatic Cholangiocarcinoma

Hepatobiliary cancers include hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC), and are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of hepatobiliary cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 40,710 new cases of these cancers were expected to be diagnosed in the United States in 2017.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of hepatobiliary cases diagnosed in the United States and Europe annually. We believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. We estimate that approximately 9,300 ICC patients in the United States and Europe annually could be candidates for treatment with Melphalan/HDS, which we believe represents a significant market opportunity.

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

About CHEMOSAT and Melphalan/HDS Kit

CHEMOSAT and Melphalan/HDS administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP® therapy), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient’s circulatory system.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT and Melphalan/HDS is repeatable, and a new disposable CHEMOSAT and Melphalan/HDS is used for each treatment. Patients treated in clinical trial settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, if we receive FDA approval, melphalan hydrochloride for injection will be included with the system and marketed as the drug/device melphalan/HDS Kit. 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.

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 is not a part of this prospectus.

RISK FACTORS

Investment in any securities offered pursuant to this prospectus and the applicable prospectus supplement involves risks. You should carefully consider the risk factors incorporated by reference to our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K we file after the date of this prospectus, and all other information contained or incorporated by reference into this prospectus, as updated by our subsequent filings under the Exchange Act, and the risk factors and other information contained in the applicable prospectus supplement and any applicable free writing prospectus before acquiring any of such securities. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

USE OF PROCEEDS

We intend to use the net proceeds from offerings under this prospectus pursuant to prospectus supplements for:

- the clinical and regulatory development of clinical studies, including the Phase 3 Ocular Melanoma liver metastases trial, a registration trial for intrahepatic cholangiocarcinoma, investigator initiated trials, and European Union Commercial Registry;
- commercialization of our products,
- obtaining regulatory approvals;
- capital expenditures;
- working capital; and
- the balance, if any, for other general corporate purposes.

We expect that the proceeds of these offerings will be sufficient to allow us to continue our ongoing clinical trial programs, however, we are subject to substantial risks that could require us to obtain additional funding in order to achieve these objectives. See “Risk Factors.” We may need substantial additional capital in the future, which could cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights, and if additional capital is not available, we may have to delay, reduce or cease operations.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation, which has been publicly filed with the SEC. See “Where You Can Find More Information; Incorporation by Reference.”

DESCRIPTION OF CAPITAL STOCK AND RECENT TRANSACTIONS

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 our 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 December 12, 2018, we had 9,082,952 shares of common stock outstanding and 101 shares of preferred stock outstanding. As of December 12, 2018, we had 66.9 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $2.99 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.

Listing

Our common stock is quoted on 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.

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, none of

which are 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.

As of the date of this prospectus, we have designated the following series of preferred stock: Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock. None of the shares of the Series A, Series B or Series C Preferred Stock are issued and outstanding. 101 shares of Series D Preferred Stock are issued and outstanding as of December 12, 2018. None of the shares of preferred stock in any of Series A, Series B, Series C or Series D is to be registered under this prospectus.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

DESCRIPTION OF SENIOR DEBT SECURITIES

The following description, together with the additional information we may include in any applicable prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the

senior debt securities that we may offer under this prospectus. While the terms summarized below will apply generally to any senior debt securities that we may offer, we will describe the particular terms of any senior debt securities in more detail in the applicable prospectus supplement. The terms of any senior debt securities offered under a prospectus supplement may differ from the terms described below.

We may issue senior debt securities from time to time in one or more distinct series. The debt securities will be senior debt securities (also referred to as "debt securities"). Senior debt securities will be issued under a senior indenture, which form of indenture is filed herewith as Exhibit 4.1. If we issue senior debt securities pursuant to an indenture, in the applicable prospectus supplement we will specify the trustee under such indenture. We will include in a supplement to this prospectus the specific terms of debt securities being offered, including the terms, if any, on which debt securities may be convertible into or exchangeable for common stock, preferred stock or other debt securities. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of debt securities and any indentures are summaries of these provisions, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the debt securities and the indentures (including any amendments or supplements we may enter into from time to time which are permitted under the debt securities or an indenture).

Unless otherwise specified in a prospectus supplement, the debt securities will be direct unsecured obligations of the Company. Any debt securities designated as senior will rank equally with any of our other senior and unsubordinated debt.

The applicable prospectus supplement will set forth the terms of the senior debt securities or any series thereof, including, if applicable:

- the title of the senior debt securities;
- any limit upon the aggregate principal amount of the debt securities;
- whether the debt securities will be issued as registered securities, bearer securities or both, and any restrictions on the exchange of one form of debt securities for another and on the offer, sale and delivery of the debt securities in either form;
- the date or dates on which the principal amount of the debt securities will mature;
- if the debt securities bear interest, the rate or rates at which the debt securities bear interest, or the method for determining the interest rate, and the date or dates from which interest will accrue;
- if the debt securities bear interest, the dates on which interest will be payable, or the method for determining such dates, and the regular record dates for interest payments;
- the place or places where the payment of principal, any premium and interest will be made, where the debt securities may be surrendered for transfer or exchange and where notices or demands to or upon us may be served;
- any optional redemption provisions, which would allow us to redeem the debt securities in whole or in part;
- any sinking fund or other provisions that would obligate us to redeem, repay or purchase the debt securities;
- if the currency in which the debt securities will be issuable is United States dollars, the denominations in which any registered securities will be issuable, if other than denominations of $1,000 and any integral multiple thereof, and the denominations in which any bearer securities will be issuable, if other than the denomination of $5,000;
- if other than the entire principal amount, the portion of the principal amount of debt securities which will be payable upon a declaration of acceleration of the maturity of the debt securities;

- the events of default and covenants relevant to the debt securities, including, the inapplicability of any event of default or covenant set forth in the indenture relating to the debt securities, or the applicability of any other events of defaults or covenants in addition to the events of default or covenants set forth in the indenture relating to the debt securities;
- the name and location of the corporate trust office of the applicable trustee under the indenture for such series of notes;
- if other than United States dollars, the currency in which the debt securities will be paid or denominated;
- if the debt securities are to be payable, at our election or the election of a holder of the debt securities, in a currency other than that in which the debt securities are denominated or stated to be payable, the terms and conditions upon which that election may be made, and the time and manner of determining the exchange rate between the currency in which the debt securities are denominated or stated to be payable and the currency in which the debt securities are to be so payable;
- the designation of the original currency determination agent, if any;
- if the debt securities are issuable as indexed securities, the manner in which the amount of payments of principal, any premium and interest will be determined;
- if the debt securities do not bear interest, the dates on which we will furnish to the applicable trustee the names and addresses of the holders of the debt securities;
- if other than as set forth in an indenture, provisions for the satisfaction and discharge or defeasance or covenant defeasance of that indenture with respect to the debt securities issued under that indenture;
- the date as of which any bearer securities and any global security will be dated if other than the date of original issuance of the first debt security of a particular series to be issued;
- whether and under what circumstances we will pay additional amounts to non-United States holders in respect of any tax assessment or government charge;
- whether the debt securities will be issued in whole or in part in the form of a global security or securities and, in that case, any depositary and global exchange agent for the global security or securities, whether the global form shall be permanent or temporary and, if applicable, the exchange date;
- if debt securities are to be issuable initially in the form of a temporary global security, the circumstances under which the temporary global security can be exchanged for definitive debt securities and whether the definitive debt securities will be registered securities, bearer securities or will be in global form and provisions relating to the payment of interest in respect of any portion of a global security payable in respect of an interest payment date prior to the exchange date;
- the extent and manner to which payment on or in respect of debt securities will be subordinated to the prior payment of our other liabilities and obligations;
- whether payment of any amount due under the debt securities will be guaranteed by one or more guarantors, including one or more of our subsidiaries;
- whether the debt securities will be convertible and the terms of any conversion provisions;
- the forms of the debt securities; and
- any other terms of the debt securities, which terms shall not be inconsistent with the requirements of the Trust Indenture Act of 1939, as amended.

This prospectus is part of a registration statement that does not limit the aggregate principal amount of debt securities that we may issue and provides that we may issue debt securities from time to time in one or more

series under the form of indenture attached to this prospectus, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities.

We intend to disclose any restrictive covenants for any issuance or series of debt securities in the applicable prospectus supplement.

DESCRIPTION OF DEPOSITARY SHARES

We may, at our option, elect to offer depositary shares rather than full shares of preferred stock. Each depositary share will represent ownership of and entitlement to all rights and preferences of a fraction of a share of preferred stock of a specified series (including dividend, voting, redemption and liquidation rights). The applicable fraction will be specified in a prospectus supplement. The shares of preferred stock represented by the depositary shares will be deposited with a depositary named in the applicable prospectus supplement, under a deposit agreement among us, the depositary and the holders of the certificates evidencing depositary shares, or depositary receipts. Depositary receipts will be delivered to those persons purchasing depositary shares in the offering. The depositary will be the transfer agent, registrar and dividend disbursing agent for the depositary shares. Holders of depositary receipts agree to be bound by the deposit agreement, which requires holders to take certain actions such as filing proof of residence and paying certain charges.

The summary of the terms of the depositary shares contained in this prospectus does not purport to be complete and is subject to, and qualified in its entirety by, the provisions of the deposit agreement and our certificate of incorporation and the certificate of designation that are, or will be, filed with the SEC for the applicable series of preferred stock.

Dividends

The depositary will distribute all cash dividends or other cash distributions received in respect of the series of preferred stock represented by the depositary shares to the record holders of depositary receipts in proportion to the number of depositary shares owned by such holders on the relevant record date, which will be the same date as the record date fixed by us for the applicable series of preferred stock. The depositary, however, will distribute only such amount as can be distributed without attributing to any depositary share a fraction of one cent, and any balance not so distributed will be added to and treated as part of the next sum received by the depositary for distribution to record holders of depositary receipts then outstanding.

In the event of a distribution other than in cash, the depositary will distribute property received by it to the record holders of depositary receipts entitled thereto, in proportion, as nearly as may be practicable, to the number of depositary shares owned by such holders on the relevant record date, unless the depositary determines (after consultation with us) that it is not feasible to make such distribution, in which case the depositary may (with our approval) adopt any other method for such distribution as it deems equitable and appropriate, including the sale of such property (at such place or places and upon such terms as it may deem equitable and appropriate) and distribution of the net proceeds from such sale to such holders.

Liquidation Preference

In the event of the liquidation, dissolution or winding up of the affairs of Delcath, whether voluntary or involuntary, the holders of each depositary share will be entitled to the fraction of the liquidation preference accorded each share of the applicable series of preferred stock as set forth in the applicable prospectus supplement.

Redemption

If the series of preferred stock represented by the applicable series of depositary shares is redeemable, such depositary shares will be redeemed from the proceeds received by the depositary resulting from the redemption, in whole or in part, of the preferred stock held by the depositary. Whenever we redeem any preferred stock held by the depositary, the depositary will redeem as of the same redemption date the number of depositary shares representing the shares of preferred stock so redeemed. The depositary will mail the notice of redemption promptly upon receipt of such notice from us and not less than 30 nor more than 60 days prior to the date fixed for redemption of the preferred stock and the depositary shares to the record holders of the depositary receipts.

Voting

Promptly upon receipt of notice of any meeting at which the holders of the series of preferred stock represented by the applicable series of depositary shares are entitled to vote, the depositary will mail the information contained in such notice of meeting to the record holders of the depositary receipts as of the record date for such meeting. Each such record holder of depositary receipts will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the number of shares of preferred stock represented by such record holder's depositary shares. The depositary will endeavor, insofar as practicable, to vote such preferred stock represented by such depositary shares in accordance with such instructions, and we will agree to take all action which may be deemed necessary by the depositary in order to enable the depositary to do so. The depositary will abstain from voting any of the preferred stock to the extent that it does not receive specific instructions from the holders of depositary receipts.

Withdrawal of Preferred Stock

Upon surrender of depositary receipts at the principal office of the depositary and payment of any unpaid amount due the depositary, and subject to the terms of the deposit agreement, the owner of the depositary shares evidenced thereby is entitled to delivery of the number of whole shares of preferred stock and all money and other property, if any, represented by such depositary shares. Partial shares of preferred stock will not be issued. If the depositary receipts delivered by the holder evidence a number of depositary shares in excess of the number of depositary shares representing the number of whole shares of preferred stock to be withdrawn, the depositary will deliver to such holder at the same time a new depositary receipt evidencing such excess number of depositary shares. Holders of preferred stock thus withdrawn will not thereafter be entitled to deposit such shares under the deposit agreement or to receive depositary receipts evidencing depositary shares therefor.

Amendment and Termination of Deposit Agreement

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may at any time and from time to time be amended by agreement between us and the depositary. However, any amendment which materially and adversely alters the rights of the holders (other than any change in fees) of depositary shares will not be effective unless such amendment has been approved by at least a majority of the depositary shares then outstanding. No such amendment may impair the right, subject to the terms of the deposit agreement, of any owner of any depositary shares to surrender the depositary receipt evidencing such depositary shares with instructions to the depositary to deliver to the holder of the preferred stock and all money and other property, if any, represented thereby, except in order to comply with mandatory provisions of applicable law.

The deposit agreement will be permitted to be terminated by us upon not less than 30 days prior written notice to the applicable depositary if a majority of each series of preferred stock affected by such termination consents to such termination, whereupon such depositary will be required to deliver or make available to each holder of depositary receipts, upon surrender of the depositary receipts held by such holder, such number of whole or fractional shares of preferred stock as are represented by the depositary shares evidenced by such depositary receipts together with any other property held by such depositary with respect to such depositary receipts. In

addition, the deposit agreement will automatically terminate if (a) all outstanding depositary shares thereunder shall have been redeemed, (b) there shall have been a final distribution in respect of the related preferred stock in connection with any liquidation, dissolution or winding-up of Delcath and such distribution shall have been distributed to the holders of depositary receipts evidencing the depositary shares representing such preferred stock or (c) each share of the related preferred stock shall have been converted into stock of Delcath not so represented by depositary shares.

Charges of Depositary

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangements. We will pay charges of the depositary in connection with the initial deposit of the preferred stock and initial issuance of the depositary shares, and redemption of the preferred stock and all withdrawals of preferred stock by owners of depositary shares. Holders of depositary receipts will pay transfer, income and other taxes and governmental charges and certain other charges as are provided in the deposit agreement to be for their accounts. In certain circumstances, the depositary may refuse to transfer depositary shares, may withhold dividends and distributions and sell the depositary shares evidenced by such depositary receipt if such charges are not paid. The applicable prospectus supplement will include information with respect to fees and charges, if any, in connection with the deposit or substitution of the underlying securities, the receipt and distribution of dividends, the sale or exercise of rights, the withdrawal of the underlying security, and the transferring, splitting or grouping of receipts. The applicable prospectus supplement will also include information with respect to the right to collect the fees and charges, if any, against dividends received and deposited securities.

Miscellaneous

The depositary will forward to the holders of depositary receipts all notices, reports and proxy soliciting material from us which are delivered to the depositary and which we are required to furnish to the holders of the preferred stock. In addition, the depositary will make available for inspection by holders of depositary receipts at the principal office of the depositary, and at such other places as it may from time to time deem advisable, any notices, reports and proxy soliciting material received from us which are received by the depositary as the holder of preferred stock. The applicable prospectus supplement will include information about the rights, if any, of holders of receipts to inspect the transfer books of the depositary and the list of holders of receipts.

Neither the depositary nor Delcath assumes any obligation or will be subject to any liability under the deposit agreement to holders of depositary receipts other than for its negligence or willful misconduct. Neither the depositary nor Delcath will be liable if it is prevented or delayed by law or any circumstance beyond its control in performing its obligations under the deposit agreement. The obligations of Delcath and the depositary under the deposit agreement will be limited to performance in good faith of their duties thereunder, and they will not be obligated to prosecute or defend any legal proceeding in respect of any depositary shares or preferred stock unless satisfactory indemnity is furnished. Delcath and the depositary may rely on written advice of counsel or accountants, on information provided by holders of the depositary receipts or other persons believed in good faith to be competent to give such information and on documents believed to be genuine and to have been signed or presented by the proper party or parties.

In the event the depositary shall receive conflicting claims, requests or instructions from any holders of depositary receipts, on the one hand, and us, on the other hand, the depositary shall be entitled to act on such claims, requests or instructions received from us.

Resignation and Removal of Depositary

The depositary may resign at any time by delivering to us notice of its election to do so, and we may at any time remove the depositary, any such resignation or removal to take effect upon the appointment of a successor

depositary and its acceptance of such appointment. Such successor depositary must be appointed within 60 days after delivery of the notice for resignation or removal and must be a bank or trust company having its principal office in the United States and having a combined capital and surplus of at least $100,000,000.

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of shares of our common stock or preferred stock or of senior debt securities. We may issue warrants independently or together with other securities, and the warrants may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and the investors or a warrant agent. The following summary of material provisions of the warrants and warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to a particular series of warrants. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. We urge you to read the applicable prospectus supplement and any related free writing prospectus, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants.

The particular terms of any issue of warrants will be described in the prospectus supplement relating to the issue. Those terms may include:

- the number of shares of common stock or preferred stock purchasable upon the exercise of warrants to purchase such shares and the price at which such number of shares may be purchased upon such exercise;
- the designation, stated value and terms (including, without limitation, liquidation, dividend, conversion and voting rights) of the series of preferred stock purchasable upon exercise of warrants to purchase preferred stock;
- the principal amount of debt securities that may be purchased upon exercise of a debt warrant and the exercise price for the warrants, which may be payable in cash, securities or other property;
- the date, if any, on and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;
- the terms of any rights to redeem or call the warrants;
- the date on which the right to exercise the warrants will commence and the date on which the right will expire;
- United States Federal income tax consequences applicable to the warrants; and
- any additional terms of the warrants, including terms, procedures, and limitations relating to the exchange, exercise and settlement of the warrants.

Holders of equity warrants will not be entitled:

- to vote, consent or receive dividends;
- receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter; or
- exercise any rights as stockholders of Delcath.

Each warrant will entitle its holder to purchase the principal amount of debt securities or the number of shares of preferred stock or common stock at the exercise price set forth in, or calculable as set forth in, the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

A holder of warrant certificates may exchange them for new warrant certificates of different denominations, present them for registration of transfer and exercise them at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement. Until any warrants to purchase debt securities are exercised, the holder of the warrants will not have any rights of holders of the debt securities that can be purchased upon exercise, including any rights to receive payments of principal, premium or interest on the underlying debt securities or to enforce covenants in the applicable indenture. Until any warrants to purchase common stock or preferred stock are exercised, the holders of the warrants will not have any rights of holders of the underlying common stock or preferred stock, including any rights to receive dividends or payments upon any liquidation, dissolution or winding up on the common stock or preferred stock, if any.

DESCRIPTION OF UNITS

We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

The following description, together with the additional information included in any applicable prospectus supplement, summarizes the general features of the units that we may offer under this prospectus. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of units being offered, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms and provisions and we will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of each unit agreement relating to units offered under this prospectus.

If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable;
- a discussion of certain United States federal income tax considerations applicable to the units; and
- any other terms of the units and their constituent securities.

GLOBAL SECURITIES

Book-Entry, Delivery and Form

Unless we indicate differently in any applicable prospectus supplement or free writing prospectus, the securities initially will be issued in book-entry form and represented by one or more global notes or global securities, or, collectively, global securities. The global securities will be deposited with, or on behalf of, The Depository Trust Company, New York, New York, as depositary, or DTC, and registered in the name of Cede & Co., the nominee of DTC. Unless and until it is exchanged for individual certificates evidencing securities under the limited circumstances described below, a global security may not be transferred except as a whole by the depositary to its nominee or by the nominee to the depositary, or by the depositary or its nominee to a successor depositary or to a nominee of the successor depositary.

DTC has advised us that it is:

- a limited-purpose trust company organized under the New York Banking Law;
- a "banking organization" within the meaning of the New York Banking Law;
- a member of the Federal Reserve System;
- a "clearing corporation" within the meaning of the New York Uniform Commercial Code; and
- a "clearing agency" registered pursuant to the provisions of Section 17A of the Exchange Act.

DTC holds securities that its participants deposit with DTC. DTC also facilitates the settlement among its participants of securities transactions, such as transfers and pledges, in deposited securities through electronic computerized book-entry changes in participants' accounts, thereby eliminating the need for physical movement of securities certificates. "Direct participants" in DTC include securities brokers and dealers, including underwriters, banks, trust companies, clearing corporations and other organizations. DTC is a wholly-owned subsidiary of The Depository Trust & Clearing Corporation, or DTCC. DTCC is the holding company for DTC, National Securities Clearing Corporation and Fixed Income Clearing Corporation, all of which are registered clearing agencies. DTCC is owned by the users of its regulated subsidiaries. Access to the DTC system is also available to others, which we sometimes refer to as indirect participants, that clear through or maintain a custodial relationship with a direct participant, either directly or indirectly. The rules applicable to DTC and its participants are on file with the SEC.

Purchases of securities under the DTC system must be made by or through direct participants, which will receive a credit for the securities on DTC's records. The ownership interest of the actual purchaser of a security, which we sometimes refer to as a beneficial owner, is in turn recorded on the direct and indirect participants' records. Beneficial owners of securities will not receive written confirmation from DTC of their purchases. However, beneficial owners are expected to receive written confirmations providing details of their transactions, as well as periodic statements of their holdings, from the direct or indirect participants through which they purchased securities. Transfers of ownership interests in global securities are to be accomplished by entries made on the books of participants acting on behalf of beneficial owners. Beneficial owners will not receive certificates representing their ownership interests in the global securities, except under the limited circumstances described below.

To facilitate subsequent transfers, all global securities deposited by direct participants with DTC will be registered in the name of DTC's partnership nominee, Cede & Co., or such other name as may be requested by an authorized representative of DTC. The deposit of securities with DTC and their registration in the name of Cede & Co. or such other nominee will not change the beneficial ownership of the securities. DTC has no knowledge of the actual beneficial owners of the securities. DTC's records reflect only the identity of the direct participants to whose accounts the securities are credited, which may or may not be the beneficial owners. The participants are responsible for keeping account of their holdings on behalf of their customers.

So long as the securities are in book-entry form, you will receive payments and may transfer securities only through the facilities of the depositary and its direct and indirect participants. We will maintain an office or agency in the location specified in the prospectus supplement for the applicable securities, where notices and demands in respect of the securities and the indenture may be delivered to us and where certificated securities may be surrendered for payment, registration of transfer or exchange.

Conveyance of notices and other communications by DTC to direct participants, by direct participants to indirect participants and by direct participants and indirect participants to beneficial owners will be governed by arrangements among them, subject to any legal requirements in effect from time to time.

Redemption notices will be sent to DTC. If less than all of the securities of a particular series are being redeemed, DTC's practice is to determine by lot the amount of the interest of each direct participant in the securities of such series to be redeemed.

Neither DTC nor Cede & Co. (or such other DTC nominee) will consent or vote with respect to the securities. Under its usual procedures, DTC will mail an omnibus proxy to us as soon as possible after the record date. The omnibus proxy assigns the consenting or voting rights of Cede & Co. to those direct participants to whose accounts the securities of such series are credited on the record date, identified in a listing attached to the omnibus proxy.

So long as securities are in book-entry form, we will make payments on those securities to the depositary or its nominee, as the registered owner of such securities, by wire transfer of immediately available funds. If securities are issued in definitive certificated form under the limited circumstances described below and unless if otherwise provided in the description of the applicable securities herein or in the applicable prospectus supplement, we will have the option of making payments by check mailed to the addresses of the persons entitled to payment or by wire transfer to bank accounts in the United States designated in writing to the applicable trustee or other designated party at least 15 days before the applicable payment date by the persons entitled to payment, unless a shorter period is satisfactory to the applicable trustee or other designated party.

Redemption proceeds, distributions and dividend payments on the securities will be made to Cede & Co., or such other nominee as may be requested by an authorized representative of DTC. DTC's practice is to credit direct participants' accounts upon DTC's receipt of funds and corresponding detail information from us on the payment date in accordance with their respective holdings shown on DTC records. Payments by participants to beneficial owners will be governed by standing instructions and customary practices, as is the case with securities held for the account of customers in bearer form or registered in "street name." Those payments will be the responsibility of participants and not of DTC or us, subject to any statutory or regulatory requirements in effect from time to time. Payment of redemption proceeds, distributions and dividend payments to Cede & Co., or such other nominee as may be requested by an authorized representative of DTC, is our responsibility, disbursement of payments to direct participants is the responsibility of DTC, and disbursement of payments to the beneficial owners is the responsibility of direct and indirect participants.

Except under the limited circumstances described below, purchasers of securities will not be entitled to have securities registered in their names and will not receive physical delivery of securities. Accordingly, each beneficial owner must rely on the procedures of DTC and its participants to exercise any rights under the securities and the indenture.

The laws of some jurisdictions may require that some purchasers of securities take physical delivery of securities in definitive form. Those laws may impair the ability to transfer or pledge beneficial interests in securities.

DTC may discontinue providing its services as securities depositary with respect to the securities at any time by giving reasonable notice to us. Under such circumstances, in the event that a successor depositary is not obtained, securities certificates are required to be printed and delivered.

As noted above, beneficial owners of a particular series of securities generally will not receive certificates representing their ownership interests in those securities. However, if:

- DTC notifies us that it is unwilling or unable to continue as a depositary for the global security or securities representing such series of securities or if DTC ceases to be a clearing agency registered under the Exchange Act at a time when it is required to be registered and a successor depositary is not appointed within 90 days of the notification to us or of our becoming aware of DTC's ceasing to be so registered, as the case may be;
- we determine, in our sole discretion, not to have such securities represented by one or more global securities; or
- an Event of Default has occurred and is continuing with respect to such series of securities.

we will prepare and deliver certificates for such securities in exchange for beneficial interests in the global securities. Any beneficial interest in a global security that is exchangeable under the circumstances described in

the preceding sentence will be exchangeable for securities in definitive certificated form registered in the names that the depositary directs. It is expected that these directions will be based upon directions received by the depositary from its participants with respect to ownership of beneficial interests in the global securities.

Euroclear and Clearstream

If so provided in the applicable prospectus supplement, you may hold interests in a global security through Clearstream Banking S.A., which we refer to as "Clearstream," or Euroclear Bank S.A./N.V., as operator of the Euroclear System, which we refer to as "Euroclear," either directly if you are a participant in Clearstream or Euroclear or indirectly through organizations which are participants in Clearstream or Euroclear. Clearstream and Euroclear will hold interests on behalf of their respective participants through customers' securities accounts in the names of Clearstream and Euroclear, respectively, on the books of their respective U.S. depositaries, which in turn will hold such interests in customers' securities accounts in such depositaries' names on DTC's books.

Clearstream and Euroclear are securities clearance systems in Europe. Clearstream and Euroclear hold securities for their respective participating organizations and facilitate the clearance and settlement of securities transactions between those participants through electronic book-entry changes in their accounts, thereby eliminating the need for physical movement of certificates.

Payments, deliveries, transfers, exchanges, notices and other matters relating to beneficial interests in global securities owned through Euroclear or Clearstream must comply with the rules and procedures of those systems. Transactions between participants in Euroclear or Clearstream, on one hand, and other participants in DTC, on the other hand, are also subject to DTC's rules and procedures.

Investors will be able to make and receive through Euroclear and Clearstream payments, deliveries, transfers and other transactions involving any beneficial interests in global securities held through those systems only on days when those systems are open for business. Those systems may not be open for business on days when banks, brokers and other institutions are open for business in the United States.

Cross-market transfers between participants in DTC, on the one hand, and participants in Euroclear or Clearstream, on the other hand, will be effected through DTC in accordance with the DTC's rules on behalf of Euroclear or Clearstream, as the case may be, by their respective U.S. depositaries; however, such cross-market transactions will require delivery of instructions to Euroclear or Clearstream, as the case may be, by the counterparty in such system in accordance with the rules and procedures and within the established deadlines (European time) of such system. Euroclear or Clearstream, as the case may be, will, if the transaction meets its settlement requirements, deliver instructions to its U.S. depositary to take action to effect final settlement on its behalf by delivering or receiving interests in the global securities through DTC, and making or receiving payment in accordance with normal procedures for same-day fund settlement. Participants in Euroclear or Clearstream may not deliver instructions directly to their respective U.S. depositaries.

Due to time zone differences, the securities accounts of a participant in Euroclear or Clearstream purchasing an interest in a global security from a direct participant in DTC will be credited, and any such crediting will be reported to the relevant participant in Euroclear or Clearstream, during the securities settlement processing day (which must be a business day for Euroclear or Clearstream) immediately following the settlement date of DTC. Cash received in Euroclear or Clearstream as a result of sales of interests in a global security by or through a participant in Euroclear or Clearstream to a direct participant in DTC will be received with value on the settlement date of DTC but will be available in the relevant Euroclear or Clearstream cash account only as of the business day for Euroclear or Clearstream following DTC's settlement date.

Other

The information in this section of this prospectus concerning DTC, Clearstream, Euroclear and their respective book-entry systems has been obtained from sources that we believe to be reliable, but we do not take

responsibility for this information. This information has been provided solely as a matter of convenience. The rules and procedures of DTC, Clearstream and Euroclear are solely within the control of those organizations and could change at any time. Neither we nor the trustee nor any agent of ours or of the trustee has any control over those entities and none of us takes any responsibility for their activities. You are urged to contact DTC, Clearstream and Euroclear or their respective participants directly to discuss those matters. In addition, although we expect that DTC, Clearstream and Euroclear will perform the foregoing procedures, none of them is under any obligation to perform or continue to perform such procedures and such procedures may be discontinued at any time. Neither we nor any agent of ours will have any responsibility for the performance or nonperformance by DTC, Clearstream and Euroclear or their respective participants of these or any other rules or procedures governing their respective operations.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods or through underwriters or dealers, through agents and/or directly to one or more purchasers. The securities may be distributed from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each time that we sell securities covered by this prospectus, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms and conditions of the offering of such securities, including the offering price of the securities and the proceeds to us, if applicable.

Offers to purchase the securities being offered by this prospectus may be solicited directly. Agents may also be designated to solicit offers to purchase the securities from time to time. Any agent involved in the offer or sale of our securities will be identified in a prospectus supplement.

If a dealer is utilized in the sale of the securities being offered by this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If an underwriter is utilized in the sale of the securities being offered by this prospectus, an underwriting agreement will be executed with the underwriter at the time of sale and the name of any underwriter will be provided in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and any discounts and commissions received by them and any profit realized by them on resale of the securities may

be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof and to reimburse those persons for certain expenses.

Any common stock will be listed on the OTCQB, but any other securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate proceeds of the offering.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

LEGAL MATTERS

Wexler, Burkhart, Hirschberg & Unger, LLP will pass upon certain legal matters relating to the issuance and sale of the securities offered hereby on behalf of Delcath Systems, Inc. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The audited consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting, incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the reports of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

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Up to $10,000,000
Common Stock

PROSPECTUS SUPPLEMENT

August 18, 2020