DELCATH SYSTEMS, INC.
Form S-1
August 15, 2018
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As filed with the Securities and Exchange Commission on August 15, 2018

No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Delcath Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

1633 Broadway

Suite 22C

New York, New York 10019

(212) 489-2100

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Jennifer K. Simpson

President and

Chief Executive Officer

Delcath Systems, Inc.

1633 Broadway

Suite 22C

New York, New York 10019

(212) 489-2100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Jolie Kahn, Esq.

Wexler, Burkhart, Hirschberg & Unger

377 Oak Street

Garden City, NY 11530

(516) 222-2230

Approximate date of commencement of proposed sale to the public:

As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate**	**Amount of registration fee**

	offering price(1)	
Common stock, $.01 par value(2)	$6,000,000	$747.00
Total	$6,000,000	$747.00

(1) Estimated solely for the purpose of calculating the registration fee under Rule 457(o) of the Securities Act.
(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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

Subject to Completion, Dated August 15, 2018

3,298,516 Shares of Common Stock

This prospectus relates to the offer and sale of up to 3,298,516 (based upon a closing price of $1.819 per share on August 10, 2018) shares of common stock of Delcath Systems, Inc., a Delaware corporation, issuable to a certain selling stockholder, upon exercise of certain warrants issued to it at an exercise price of $0.01 per share which warrants were issued and exercise price prepaid pursuant to a Securities Purchase Agreement between the Company (as defined below) and this selling stockholder, dated June 4, 2018.

This prospectus covers any additional shares of common stock that may become issuable by reason of stock splits, stock dividends, and other events described therein.

Unless otherwise noted, the terms the Company, our Company, Delcath, we, us and our refer to Delcath Syst and its subsidiaries.

The selling stockholder may offer its shares from time to time directly or through one or more underwriters, broker-dealers or agents, in the over-the-counter market at market prices prevailing at the time of sale, in one or more privately negotiated transactions at prices acceptable to the selling stockholder, or otherwise, so long as our common stock is trading on the Nasdaq Capital Market or the OTCQB, and if it is not trading on the OTCQB, OTCQX or a listed exchange, sales may only take place at fixed prices.

We are registering these shares of our common stock for resale by the selling stockholder named in this prospectus, or its transferees, pledgees, donees or assigns or other successors-in-interest that receive any of the shares as a gift, distribution, or other non-sale related transfer. We will not receive any proceeds from the sale of shares by the selling stockholder. These shares are being registered to permit the selling stockholder to sell shares from time to time, in amounts, at prices and on terms determined at the time of offering. The selling stockholder may sell this common stock through ordinary brokerage transactions, directly to market makers of our shares or through any other means described in the section entitled PLAN OF DISTRIBUTION beginning of page 87. In connection with any sales of the common stock offered hereunder, the selling stockholder, any underwriters, agents, brokers or dealers participating in such sales may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended (the Securities Act).

We will pay the expenses related to the registration of the shares covered by this prospectus. The selling stockholder will pay any commissions and selling expenses they may incur.

Our common stock trades on the OTCQB under the symbol DCTJ . The closing sale price on the OTCQB on August 10, 2018, was $1.819 per share.

Our principal executive offices are located at 1633 Broadway, Suite 22C, New York, NY 10019. Our telephone number at that address is (212) 489-2100.

Investing in the common stock offered by this prospectus is speculative and involves a high degree of risk. See Risk Factors beginning on page 5.

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 , 2018

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this document, regardless of the time of delivery of this prospectus or the time of issuance or sale of any securities. Our business, financial condition, results of operations and prospects may have changed since that date. You should read this prospectus in its entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus entitled Where You Can Find More Information.

For investors outside of the United States, neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

Industry and Market Data

This prospectus includes industry data and forecasts that we obtained from industry publications and surveys, public filings and internal company sources. Industry publications and surveys and forecasts generally state that the

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

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PROSPECTUS SUMMARY

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

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 for CHEMOSAT and Melphalan/HDS is comprised, in part, of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial), a Global Phase 3 clinical trial that is investigating overall survival in mOM. We have also initiated a separate clinical trial that also uses Melphalan/HDS Kit for intrahepatic cholangiocarcinoma (ICC). Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

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.

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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, suchas 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.

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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.

Risks of Investing

Investing in our securities involves substantial risks. Potential investors are urged to read and consider the risk factors relating to an investment in the common stock set forth under Risk Factors in this prospectus as well as other information we include in this prospectus.

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.

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SUMMARY OF THE OFFERING

Common stock offered by the selling stockholder:	Up to 3,298,516 shares of our common stock, par value $0.01 per share, are being offered by the selling stockholder.
Offering prices:	The shares offered by this prospectus may be offered and sold at prevailing market prices or such other prices as the selling stockholder may determine.
Common stock outstanding:	932,159 shares as of August 10, 2018(*).
OTCQB:	DCTH for common stock.
Use of proceeds:	We are not selling any of the shares of common stock being offered by this prospectus and will receive no proceeds from the sale of the shares by the selling stockholder. All of the proceeds from the sale of common stock offered by this prospectus will go to the selling stockholder at the time it sells its shares.

(*) The total number of shares of our common stock outstanding after this offering is based on 932,158 shares outstanding as of August 10, 2018. Excludes as of that date, the following:
25.2 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.76 per share.

Reverse Stock Split	On May 2, 2018, we effected a 1-for-500 reverse stock split of our outstanding shares of common stock.
Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.
OTCQB symbol for common stock	DCTH
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities
Transfer agent and registrar	American Stock Transfer and Trust Company, LLC

The number of shares of our common stock outstanding prior to and immediately after this offering, as set forth above, excludes the following potentially dilutive securities as of August 10, 2018:

25.2 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.76 per share

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RISK FACTORS

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

Risks Related to Our Business and Financial Condition

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

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Delcath received a complete response letter from the FDA regarding our Melphalan/HDS Kit system, 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 New Drug Application (NDA), which the Company submitted to FDA in August 2012 seeking approval for use of our Melphalan/HDS Kit for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its current form and issued a complete response letter (CRL). A CRL is issued by the FDA when the review of a file is completed, and questions remain that preclude approval of the NDA in its current form. The FDA comments in the CRL included, but were not limited to, a statement that Delcath must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS Kit using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS Kit outweigh its risks. The FDA also required that the additional clinical trial(s) be conducted using the product the company intends to market. Prior to conducting additional clinical trials, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. Further, in January 2016 Delcath received agreement on a Special Protocol Assessment (SPA) from the FDA and has initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases.

A SPA is a process whereby a sponsor and FDA reach agreement on clinical trials and protocol elements, as well as planned analyses. While a SPA agreement is not a guarantee that FDA will accept a NDA for filing or that the clinical trial design and results will be adequate to support approval it is hoped that clinical trial quality will be improved.

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In addition, Delcath conducts and participates in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for Melphalan/HDS Kit and HDS with other drug therapies. In 2014, Delcath initiated a Phase 2 clinical trial with Melphalan/HDS Kit for 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 ICC. The trial for this cohort will be 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 this clinical data or FDA s perception of this clinical data, may adversely impact our ability to obtain approval, and the financial condition. Additionally, even if the results of our Phase 2 clinical trial for HCC and ICC are positive, there is a substantial risk that it will fail to have positive results in Phase 3 clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

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

Our former independent registered public accounting firm issued a report dated March 16, 2018 in connection with the audit of our financial statements as of December 31, 2017, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, our notes to our financial statements for the year ended December 31, 2017 included a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, Delcath would be forced to delay, reduce or eliminate its research and development programs or any commercialization efforts. The Company s consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If the Company is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment.

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

Delcath s entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT/Melphalan/HDS and currently has only developed this system for the treatment of cancers in the liver. If CHEMOSAT/Melphalan/HDS for the treatment of cancers in the liver fails as a commercial product, the Company has no other products to sell. In addition, since CHEMOSAT is currently only authorized for marketing in the EEA and limited other jurisdictions, if Delcath is unsuccessful in commercializing the product in the EEA and if Melphalan/HDS is not approved in the United States and elsewhere, there will be no means of generating revenue. In September 2013, the FDA issued a CRL with respect to the Company s NDA for Melphalan/HDS. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude approval of the NDA in its then current form. Accordingly, Delcath does not expect to realize any revenues from product sales in the United States in the next several years, if at all. As a result, our revenue sources are, and will remain, extremely limited until the Company s product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT/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, 2018, the Company had $1.3 million in cash and cash equivalents. Delcath has had minimal revenue to date, and has a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2017, 2016 and 2015, the Company incurred net losses of approximately $45.1 million, $18.0 million

and $14.7 million, respectively and expects to continue to incur losses in 2018. Management believes its capital resources are adequate to fund operations through July 2018, without giving effect to the offering contemplated hereby. To date, the Company has funded operations through a combination of private placements and public offerings of its securities, including convertible notes. If Delcath continues to

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incur losses, the Company may exhaust its capital resources, and as a result may be unable to complete its clinical trials, product development, regulatory approval process and commercialization of CHEMOSAT/Melphalan/HDS or any other versions of the system. If Delcath is unable to raise capital or generate sufficient revenue, it may not be able to pay its debts when they become due and may have to seek protection from the bankruptcy courts or enter into a receivership.

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

The Company will require additional financing to complete its clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize its product in the EEA and any other markets where the Company may receive approval for its system. In addition, Delcath is obligated to make payments under long-term research and development obligations and lease agreements. If financing is unavailable to make the required payments under these agreements, the Company could be subject to legal liability and its ability to complete development projects or clinical trials could be impaired. The Company does not know if additional financing will be available when needed at all or on acceptable terms. If unable to obtain additional financing as needed, the Company may not be able to commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete its development projects or clinical trials, which would result in a complete loss of your investment.

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

- clinical studies, including a Phase 3 clinical trial to investigate overall survival in ocular melanoma liver metastases and a registration trial in ICC;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, regulatory submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

CHEMOSAT and Melphalan/HDS is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to either civil or criminal administrative or judicially-imposed sanctions and/or other penalties.

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In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Melphalan/HDS is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product s primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

The Company is not permitted to market Melphalan/HDS in the United States unless and until it obtains regulatory approval from the FDA. To market the product in the United States, Delcath must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and the Company could encounter problems that cause it to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

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

Undesirable side effects caused by any product candidate that Delcath develops could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, the Company submitted the Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA declined to approve the NDA and

issued a CRL. The FDA comments in the CRL included, but were not limited to, a statement that the Company must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. Prior to conducting additional clinical trials, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. However, even if the Company completes its clinical trials and satisfies all the requirements of the CRL, it may not obtain regulatory approval from the FDA. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

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adversely affect the commercialization of the current version of CHEMOSAT and Melphalan/HDS or any products that the Company develops in the future;

impose additional costs on Delcath;

diminish any competitive advantages that may be attained; and

adversely affect the Company s ability to generate revenues.

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

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

The Company is limited to marketing CHEMOSAT in the EEA as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, Delcath s ability to commercialize CHEMOSAT in the EEA will be significantly limited. Delcath s product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference Delcath s product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with Delcath s device may not be within the applicable label with respect to some indications in some Member States of the EEA where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from CHEMOSAT and/or to prescribe the use of melphalan independently, the Company s sales opportunities in the EEA will be significantly impaired.

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

In April 2012, the Company obtained the required certification from its European Notified Body, enabling Delcath to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Generation Two CHEMOSAT system. In order to maintain the right to affix the CE Mark in the EEA, the Company is subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, the Company is subject to ongoing audits by its European Notified Body, and the right to affix the CE Mark to the Generation Two CHEMOSAT system may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that CHEMOSAT or Melphalan/HDS is approved by the FDA or any other regulatory agency, Delcath will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, the Company may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices (GCPs), and good laboratory practices, which are regulations

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and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that the Company conducts post-approval. In addition, post-marketing requirements for CHEMOSAT and Melphalan/HDS may include implementation of a risk evaluation and mitigation strategies (REMS) program to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If the Company is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on the business, results of operations, financial condition and prospects.

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

The Company cannot sell or market Melphalan/HDS with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for Melphalan/HDS. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of

administration of melphalan or other chemotherapeutic agent used in our system. The Company is seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. Delcath must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with the system that Delcath intends to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA s satisfaction the product s safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of Melphalan/HDS with melphalan or any other chemotherapeutic agent or compound the Company uses in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. Delcath may encounter delays or rejections for various reasons, including its inability to enroll enough patients to complete the clinical trials. Moreover, approval policies or regulations may change. If the Company does not obtain and maintain regulatory approval for its system and the use of melphalan or other chemotherapeutic agents, the value of the Company, results of operations and its ability to raise additional capital will be harmed. In August 2012, Delcath submitted an NDA seeking an indication for ocular

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melanoma liver metastases for our Melphalan/HDS. In September 2013, the FDA issued a CRL. The FDA comments in the CRL included a statement that the Company must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. Failure to obtain FDA approval will have a material adverse effect on Delcath s business, financial condition and results of operations.

Even if the Company obtains regulatory approval for the Melphalan/HDS system in the United States, its ability to market the Melphalan/HDS system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. If the FDA approves an application for the Melphalan/HDS, our ability to market and promote the Melphalan/HDS would be limited to the approved indication, so even with FDA approval, the Melphalan/HDS system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, the Company may only market the Melphalan/HDS, if approved by the FDA, for its approved indication and could be subject to enforcement action for off-label marketing. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, Delcath may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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

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

In January 2016 the Company received agreement on a SPA from the FDA and has initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases. In March 2017, Delcath received agreement on a SPA from the FDA for a registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), a trial the Company expects to initiate when financial resources permit.

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 pare-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;

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the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

Delcath may encounter delays or rejections based on changes in regulatory agency policies during the period in which it is developing a system or the period required for review of any application for regulatory agency approval;

the Company s clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;

the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase 3 trial, relating to the Company s NDA submissions;

the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay Delcath s ability to bring a system to market or require additional clinical trials; and

a system may not be approved for all the requested indications.

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

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

The Company designs the clinical trials for Melphalan/HDS, but relies on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. Delcath relies heavily on these parties for the execution of its clinical studies and control only certain aspects of their activities. Accordingly, the Company may have less control over the timing and other aspects of these clinical trials than if Delcath conducted them entirely on their own. The Company relies upon third parties to conduct monitoring and data collection of its ongoing and future clinical trials, including its Phase 3 ocular melanoma trial and pivotal ICC trial. Although Delcath relies on these third parties to manage the data from these clinical trials and are responsible for confirming that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require Delcath to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. The Company s reliance on third parties does not relieve it of these responsibilities and requirements, and if Delcath or the third parties upon whom the

Company relies for its clinical trials fail to comply with the applicable GCPs, the data generated in its clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require Delcath to perform additional trials before approving our marketing application. The Company cannot assure you that, upon inspection, the FDA will determine that any of its clinical trials comply or complied with GCPs. In addition, Delcath s clinical trials must be conducted with product that complies with the FDA s cGMP requirements. The Company s failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for Melphalan/HDS if these requirements are not met.

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

The Company has obtained the right to affix the CE Mark for CHEMOSAT, and Delcath intends to seek third-party or government reimbursement within those countries in the EEA where it expects to market and sell CHEMOSAT. In Germany, the Company has received a ZE diagnostic-related group code, which permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures beginning in 2016. Negotiations on the amount of reimbursement to be received under the code were concluded in 2016 and the procedure is reimbursed under this system in 2017. The ZE system is an annual process and negotiations are underway to set reimbursement levels for 2018. Consequently, reimbursement obtained may not be for the full amount sought. In countries where Delcath is able to obtain reimbursement, local policy could limit the Company s ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until Delcath obtains government reimbursement, it will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that Delcath will qualify for such funding. Even if the Company does qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of Member States of the EEA will reimburse the product s use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

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

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

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT/ Melphalan/HDS and the demand for CHEMOSAT/ Melphalan/HDS. Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies. In March 2010, the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (ACA) were enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. The President and members of Congress have recently introduced legislative proposals

to significantly alter the ACA. It is uncertain if such proposals will be enacted or what consequences these proposals or the implementation of existing provisions will have on our efforts to commercialize CHEMOSAT and Melphalan/HDS.

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

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

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

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

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

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

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

Under the current regulatory scheme in the EEA, CHEMOSAT is approved for marketing as a device only, and doctors will separately obtain melphalan for use with CHEMOSAT. Although melphalan has been approved in the EEA for over a decade, the Company is aware that there are currently three approved manufacturers of melphalan in certain countries of the EEA. As a result, there may not be sufficient supply of melphalan for use with its system, and any adverse change in the sole manufacturer s commercial operations or regulatory approval status may seriously impair Delcath s sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where Delcath may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, the Company will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

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

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

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

We manufacture CHEMOSAT and Melphalan/HDS for distribution worldwide in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in sufficient commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver CHEMOSAT 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 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.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble CHEMOSAT and Melphalan/HDS in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

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

The Company does not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If Delcath is unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, it may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and Melphalan/HDS in the EEA may be delayed. In addition, certain components are available from only a limited number of sources.

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Components of CHEMOSAT and Melphalan/HDS are currently manufactured for Delcath in small quantities and may require significantly greater quantities to further commercialize the product. The Company may not be able to find alternate sources of comparable components. If Delcath is unable to obtain adequate supplies of components from existing suppliers or needs to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and Melphalan/HDS may be delayed.

The Company has limited experience in marketing and commercializing its products, and as a result, may not be successful in commercializing CHEMOSAT in the EEA.

The Company has not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though Delcath has obtained the right to affix the CE Mark, it currently has limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue the Company s strategy to commercialize CHEMOSAT in the EEA, Delcath must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If Delcath cannot successfully develop the infrastructure to market and commercialize CHEMOSAT, its ability to generate revenues in the EEA may be harmed, and Delcath may not generate sufficient revenue to sustain its business or may be required to enter into strategic alliances to have such activities carried out on its behalf, which may not be on favorable terms.

Competition for sales and marketing personnel is intense, and Delcath may not be successful in attracting or retaining such personnel. The Company s inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect its business, financial condition and results of operations. Further, since Delcath s marketing strategy in the EEA includes establishing a network of third-party distributors, the Company must enter into collaborative arrangements with these third-party distributors. The Company may not be able to enter into such arrangements on reasonable terms or at all.

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

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

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

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

The Company may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, Delcath may face competition in its search for alliances. As a result, the Company may not be able to enter into any additional

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

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

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

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to satisfy foreign regulatory requirements to market its products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that the Company establishes with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;

- the possibility that foreign countries may impose additional withholding taxes or otherwise tax its foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If the Company fails to overcome the challenges it encounters in its international operations, Delcath s business and results of operations may be materially adversely affected.

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CHEMOSAT has been used a limited number of times in a clinical setting in the EEA, so market acceptance of CHEMOSAT will depend on EEA healthcare professionals efforts to learn about the product.

Since all of the Company s prior clinical studies were conducted in the United States and CHEMOSAT has had limited use in a clinical setting in the EEA, physicians in the EEA have limited clinical experience with the product. As a result, CHEMOSAT may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors in the EEA until healthcare professionals are properly educated about the procedure. Market acceptance of CHEMOSAT in the EEA will depend upon a variety of factors including:

- whether future clinical trials demonstrate significantly improved patient outcomes;
- the Company s ability to educate and train physicians to perform the procedure and drive acceptance of the use of CHEMOSAT;
- Delcath s ability to obtain adequate reimbursement and convince healthcare payors that use of CHEMOSAT results in reduced treatment costs and improved outcomes for patients;
- whether CHEMOSAT replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology s value has been demonstrated.

The Company intends to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in the EEA, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop. Without effort from healthcare professionals to become educated about Delcath s product, the market may not accept CHEMOSAT and its efforts to commercialize CHEMOSAT in the EEA may be unsuccessful.

Similar considerations apply in any other market where the Company receives approval. Successful commercialization of CHEMOSAT in these markets will depend on market acceptance by healthcare professionals.

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

Competition in the cancer treatment industry is intense. CHEMOSAT and Melphalan/HDS competes with all forms of liver cancer treatments that are alternatives to the gold standard treatment of surgical resection. Many of the Company s competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, Delcath s revenues or profitability will be substantially reduced.

The Company s ability to develop CHEMOSAT and Melphalan/HDS for other indications could affect its orphan drug exclusivity. Delcath has the following six designations:

- two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma (November 2008)
- orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors (May 2009)
- orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer (August 2009)
- orphan drug designation of the drug melphalan for the treatment of HCC (October 2013)
- orphan drug designation of the drug melphalan or the treatment of ICC (July 2015)

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If CHEMOSAT and Melphalan/HDS are approved for an indication different than the indications for which Delcath has received orphan drug designations, the Company will not obtain orphan drug exclusivity, which could increase its competition. If another company has orphan drug designations for these same indications and receives marketing approval before Delcath does, then the Company will be blocked from marketing approval for seven years from the date of its approval for the same indication of use.

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

The loss of a member of the Company s senior executive staff could harm its business. Competition for experienced personnel is intense. If Delcath cannot retain its current personnel or attract additional experienced personnel, Delcath s ability to compete could be adversely affected.

We have had a legal proceeding filed against us, and it is premature to assess what the potential outcome of the proceeding will be, and what impact, if any, the outcome could have on our business.

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the Suit). The Suit alleges breaches by the Company of Hudson Bay s rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. While the Company denies any liability with respect to the claims set forth in the Suit, it is premature to assess the outcome of this proceeding, and what, if any, impact any potential outcome could have on our business operations or financial condition.

The Backstop Agreement (as defined below) entered into on June 4, 2018 does not obligate the backstop investors to invest the full balance of the $50,000,000 not subscribed to under our current rights offering unless certain conditions are met as described in this prospectus, so we cannot be assured that we will receive the entire $50,000,000 rights offering amount.

On June 4, 2018, we entered into a Backstop Commitment Purchase Agreement with the selling stockholder, and on July 20, 2018 Discover Growth Fund, LLC entered into the same form of agreement with us (the Backstop Agreement). Pursuant to the Backstop Agreement, the investors have agreed, subject to customary conditions outside of its control, to purchase from us, on a fully committed basis, shares of common stock that would have been delivered to our stockholders upon exercise of rights that are not duly exercised prior to the expiration date of the rights offering. Such shares will be purchased for an aggregate amount equal to the aggregate subscription price and otherwise on the same terms as the shares offered to stockholders in the rights offering. Within two business days following the satisfaction of the closing conditions contained in the Backstop Agreement, and each successive 15 business day period thereafter during the term of the Backstop Agreement, the investors have agreed to purchase from us up to such number of shares equal to the lesser of (i) $1,000,000 worth of shares or (ii) 20% of the dollar trading volume of our common stock on the five trading days immediately preceding the purchase date. Therefore, if our dollar trading volume is limited as the result of either low volume in the market for our common stock, or as a result of a decrease in the market price of our common stock, we may not be able to cause the investors to purchase the full amount of the backstop commitment on or before the termination date of the Backstop Agreement, which is on or before June 30, 2019, nor may we be able to register the shares of common stock to be sold pursuant to the Backstop Agreement in full or part or at all. Any failure to receive the full $50,000,000 (inclusive of the proceeds from this rights offering) may cause a material adverse effect on our ability to fund our operations and complete our clinical trials.

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

Moreover, the United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

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

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

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

any patents we obtain or license from others in the future may not be valid or enforceable; and

we may not develop additional proprietary technologies that are patentable

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in the CHEMOSAT/Melphalan/HDS methods and/or devices that cause

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such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

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

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our CHEMOSAT/Melphalan/HDS methods and devices, we may be open to competition from generic versions of such methods and devices.

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, or may allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor s patents, we could be prevented from marketing our product in one or more foreign countries.

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT/Melphalan/HDS could be found to infringe these patents. It is also possible that our competitors or

potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

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Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor s patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others patent rights, which may not be possible or could require substantial funds or time.

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

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

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT/Melphalan/HDS or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our United States patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications,

have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

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

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

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

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

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

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

We rely on our trademarks as one means to distinguish our product from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand

recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

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

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Specifically in the European Economic Area (EEA), we rely on design patent and trade secret protection for CHEMOSAT/Melphalan/HDS. Without utility patent protection in the EEA covering the current version of CHEMOSAT/Melphalan/HDS, CHEMOSAT/Melphalan/HDS will only be covered by design patent and trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to CHEMOSAT/Melphalan/HDS will significantly impair our ability to commercialize CHEMOSAT in the EEA, and our value and results of operations will be harmed. In particular, we rely on trade secret protection for the filter media, which is a key component of our system.

Similar considerations apply in other foreign countries not mentioned above in the Intellectual Property and Other Rights section where we receive approval. Since we do not have issued patents for the current version of CHEMOSAT/Melphalan/HDS in these countries, our ability to successfully commercialize CHEMOSAT/Melphalan/HDS will depend on our ability to maintain trade secret protection in these markets.

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

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information,know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other

proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to

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paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

Risks Related to Products Liability

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

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

Risks Related to Delcath s Common Stock

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

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

- fluctuations in quarterly operating results or the operating results of competitors;

variance in financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of its markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;

failure of its products to achieve or maintain market acceptance or commercial success;

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conditions and trends in the markets served;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of competitors;

changes in pricing policies or the pricing policies of competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by the Company or its competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving Delcath, its general industry or both;

recruitment or departure of key personnel;

changes in capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of common stock by stockholders; and

the trading volume of Delcath s common stock.

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

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

The 1.0 million warrants issued in the Company s February 2015, July 2015 and October 2016 offerings, and in a transaction signed in November 2017 are subject to an exercise price adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting Delcath s common stock, and adjusted as a result of the June 2018

private placement, pursuant to which the exercise price as readjusted to $0.01. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. In addition to the potential dilutive effect of this provision, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of Delcath s common stock.

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

The Company is not restricted from issuing additional shares of common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of August 10, 2018, the Company had an aggregate of 1 billion shares of common stock authorized and of that 999.1 million not issued or outstanding, including 25.2 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $7.76. The Company may issue all of these shares without any action or approval by its shareholders. Delcath may expand its business through complementary or strategic business combinations or acquisitions of other companies and assets, and may issue shares of common stock in connection with those transactions. The market price of Delcath s common stock could decline as a result of the issuance of a large number of shares of common stock, particularly if the per share consideration received for the stock issued is less than the per share book value of Delcath s common stock or if the Company is not expected to be able to

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generate earnings with the proceeds of the issuance that are as great as the earnings per share generated before the issuance of the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by investors. The Company cannot predict the size of future issuances or the effect, if any, that they may have on the market price of its common stock.

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

Since Delcath s initial public offering in 2000, it has executed four reverse stock splits, for a cumulative ratio since its IPO of 1:44,800,000. Each such reverse split (except for the most recent reverse stock split effected on May 2, 2018) has resulted in an effective decline in the price of Delcath s common stock. For example, the most recent reverse split of 1:350 was effected on November 6, 2017, resulting in an opening price of $10.50. By November 30, 2017, Delcath s common stock closed at $0.09 and has continued to decline. On May 2, 2018, Delcath effected a 1:500 reverse split of its common stock, resulting in an opening price of $2.50. Although as of the close of the trading day on August 10, 2018, the price was $1.819, there can be no assurance that such reverse split will not result in a further significant diminution of the value of Delcath s common stock.

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

Certain provisions of the Company s Certificate of Incorporation and By-laws could have the effect of making it more difficult for its stockholders to replace management at a time when a substantial number of stockholders might favor a change in management. These provisions include:

providing for a staggered board; and

authorizing the board of directors to fill vacant directorships or increase the size of its board of directors. Furthermore, Delcath s board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The board s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of Delcath s common stock.

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

Trading in the Company s common stock is subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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

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

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

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

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

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

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

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

Failure of our products to achieve or maintain market acceptance or commercial success;

fluctuations in our quarterly operating results or the operating results of our competitors;

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variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt or the prospect of future reverse stock splits;

actual or expected sales of our common stock by our stockholders; and

the trading volume of our common stock.

In addition, the stock markets, in general, and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in

our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management s attention and resources, which could further materially harm our financial condition and results of operations.

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

The 1.0 million warrants issued in our February 2015, July 2015 and October 2016 offerings, and in a transaction signed in November 2017 are subject to an exercise price adjustment as a result of the June 2018 private placement, pursuant to which the exercise price as readjusted to $0.01. In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

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

Certain provisions of our Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of our stockholders might favor a change in management. These provisions include:

providing for a staggered board; and

authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

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Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

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

We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

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

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

issue equity securities that would dilute our current stockholders percentage ownership;

incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;

assume substantial actual or contingent liabilities;

reprioritize our programs and even cease development and commercialization of CHEMOSAT 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.

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

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of August 10, 2018, we had an aggregate of 1 billion shares of common stock authorized and of that 999.1 million not issued or outstanding, including 25.2 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $7.76. We may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic business combinations or

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acquisitions of other companies and assets, and we may issue shares of common stock in connection with those transactions. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, will, may, can, continue, potential, should, and the negative of these terms or other comparable terminology 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, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 in Item 1A under Risk Factors as well as in Item 7A Quantitative and Qualitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and System;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this

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.

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USE OF PROCEEDS

We are not selling any of the shares of common stock being offered by this prospectus and will receive no proceeds from the sale of the shares by the selling stockholder. All of the proceeds from the sale of common stock offered by this prospectus will go to the selling stockholder at the time they offer and sell such shares. We will bear all costs associated with registering the shares of common stock offered by this prospectus.

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PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is quoted on the OTCQB under the symbol DCTH. The table below sets forth, for the periods indicated, the quarterly high and low sale prices per share of our common stock since 2015. The information in the table below reflects a one-for-three hundred fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse split effected on May 2, 2018.

	High	Low
2015:		
First Quarter	$ 4,368,250	$ 2,688,000
Second Quarter	4,032,000	2,268,000
Third Quarter	2,576,000	1,120,000
Fourth Quarter	1,736,000	1,092,000
2016:		
First Quarter	$ 1,512,000	$ 700,000
Second Quarter	997,500	644,000
Third Quarter	806,750	434,000
Fourth Quarter	479,500	157,500
2017:		
First Quarter	$ 152,250	$ 14,000
Second Quarter	47,250	3,500
Third Quarter	36,265	9,615
Fourth Quarter	25,175	15
2018:		
First Quarter	$ 26	$ 5
Second Quarter	6	1

The last reported trading price of our common stock on August 10, 2018 was $1.819. As ofAugust 10, 2018, we had approximately 100 holders of record 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 currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.

Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of December 31, 2017, about our equity compensation plans (including the potential effect of debt instruments convertible into common stock) in effect as of that date:

Plan category	(a) Number of securities	(b) Weighted-average exercise	(c) Number of securities

	to be issued upon exercise of outstanding options, warrants and rights[1][2]	price of outstanding options[1]	remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))[1]
Equity compensation plans approved by security holders		$	
Equity compensation plans not approved by security holders			
Totals		$	

(1) Reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse split effected on May 2, 2018.
(2) Net of equity instruments forfeited, exercised or expired.

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OUR BUSINESS

Unless the context otherwise requires, all references in this Prospectus to the Company , Delcath , Delcath Systems , w our , and us refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100.

About Delcath

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

Our 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.

Our clinical development program for CHEMOSAT and 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 overall survival in mOM, and a registration trial for intrahepatic cholangiocarcinoma (ICC) which was initiated in May 2018. Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

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, commercialCHEMOSAT cases performed on patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and United States regulatory activity has led to the implementation of several safety improvements to our product and the associated medical procedure.

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

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing reimbursement coverage for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

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

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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 we commissioned 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. Based on the research conducted in 2016, 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%.

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About CHEMOSAT and Melphalan/HDS

CHEMOSAT and Melphalan/HDS administer 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 settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included with the system. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Risks associated with the CHEMOSAT and Melphalan/HDS Procedure

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

Procedure and Product Refinements

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

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2017, physicians in Europe and the United States also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

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Phase 3 Melanoma Metastases Trial

In February 2010, we concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melphalan/HDS, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately four to eight week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, we announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan/HDS for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study s primary endpoint of extended hepatic progression-free survival (hPFS). An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization and the European Society of Medical Oncology in September 2011. Data submitted in October 2012 to the FDA in Delcath s New Drug Application (NDA) comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the PHP arm had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the BAC control group, according to the Independent Review Committee (IRC) assessment. This reflects a 4-fold increase of hPFS over that of the BAC arm, with 50% reduction in the risk of progression and/or death in the PHP treatment arm compared to the BAC control arm. Results of this study were published in Annals of Surgical Oncology, in December 2015.

Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

Also, in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using an early version of the Melphalan/HDS in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), ocular or cutaneous melanoma, metastatic colorectal adenocarcinoma (mCRC), and HCC. In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 42%, with 66% of patients achieving hepatic tumor shrinkage and durable disease stabilization. In the mCRC cohort, there was inconclusive efficacy possibly due to advanced disease status of the patients. Similar safety profiles were seen across all tumor types studied in the trial.

Phase 2 Multi-Histology Clinical Trial HCC Cohort

In the HCC cohort (n=8) of our Phase 2 Multi-Histology trial, a positive signal in hepatic malignancies was observed in 5 patients. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hPFS ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and OS in this limited number of patients exceeded that generally associated with this patient population.

Prior United States Regulatory Experience

Based on the results from our prior clinical development in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food Drug Cosmetic Act (FFDCA) seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication to ocular melanoma metastatic to the liver. Data submitted to the Food and

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

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On May 2, 2013 we announced that an *Oncologic Drug Advisory Committee* (ODAC) panel convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of Melphalan/HDS did not outweigh the risks associated with the procedure. A significant portion of FDA s presentation to the ODAC panel was focused on the FDA s assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension (low blood pressure) during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression. We believe that the protocol amendments and other procedure refinements instituted during clinical trials and subsequently in commercial, non-clinical usage in Europe, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials in our current CDP.

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

2013 Complete Response Letter

In September 2013 the FDA issued a complete response letter (CRL) in response to our NDA. The FDA issues a CRL after the review of a file has been completed and questions remain that preclude approval of the NDA in its current form. The FDA comments included, but were not limited to, a statement that Delcath must perform another well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure, and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. The FDA also required that the additional clinical trial(s) be conducted using the product the Company intends to market, and that certain clinical, clinical pharmacology, human factors and product quality elements of the CRL be addressed.

In January 2016, we announced the conclusion of a Special Protocol Assessment (SPA) with the FDA on the design of a new Phase 3 clinical trial of Melphalan/HDS to treat patients with hepatic dominant ocular melanoma. This SPA provides agreement that our new Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the entire data in the application. The SPA agreement also represents the satisfactory resolution of a substantial number of the FDA s CRL non-clinical trial related requirements in that without these successful resolutions, the SPA request would not have been permitted to be filed.

Current Clinical Development Program

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

(the FOCUS Trial) - NCT02678572

In January 2016, we initiated a new pivotal Phase 3 clinical trial officially entitled *A Randomized, Controlled, Phase 3 Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma*. Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety,

efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial s treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

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

The FOCUS Trial is being conducted under a SPA we negotiated with the FDA in January 2016, and the first patient was enrolled in February 2016. In 2017, enrollment in this trial proceeded more slowly than anticipated, and cash constraints during the second half of the year limited our ability to take steps to accelerate enrollment In January 2018 we announced a SPA modification agreement with the FDA to revise the patient eligibility criteria to permit a greater extent of extra-hepatic disease by removing the size restriction, number and location of extra-hepatic lesions, in conjunction with a treatment plan for the extra-hepatic metastases. We hope that once approved by the institutional review boards of our participating clinical trial sites, this modification will help accelerate enrollment in this registrational trial. Any impact on enrollment of the SPA modification is not expected to be immediate, and it is unlikely that enrollment for this trial will be completed in time to submit an NDA to FDA in 2019.

Under the terms of the SPA, the FOCUS Trial is the only Phase 3 trial required for submission of an NDA. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

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

Percutaneous Hepatic Perfusion (PHP) vs. Cisplatin/Gemcitabine in Patients with Intrahepatic Cholangiocarcinoma (The ALIGN Trial) - NCT03086993

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

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

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

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

Protocol 202 NCT02415036 - Conducted in Europe, this trial is intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial will also evaluate overall response rate via mRECIST criteria, progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. This trial is now closed to enrollment.

ICC Cohort - In 2015 we expanded *Protocol 202* to include a cohort of patients with ICC. The trial for this cohort is being conducted at the same centers participating in the Phase 2 HCC trial. This trial has completed enrollment and data collection for the ICC cohort is ongoing. We will announce results for this cohort once the data are fully mature.

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

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

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy. A substantial portion of the Company s operating expenses consist of research and development expenses incurred in connection with its clinical trials. See the Company s Consolidated Financial included in Item 8 of this Annual Report on Form 10-K.

European Investigator Initiated Trials

In addition to the clinical trials in our CDP, we are supporting data generation in other areas. We are currently conducting one Investigator Initiated Trial (IIT) in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in the Netherlands. We are planning two additional IITs one for colorectal carcinoma metastatic to the liver at Heidelberg University in Heidelberg, Germany and one for pancreatic carcinoma metastatic to the liver at Spire Hospital in Southampton, England. We continue to evaluate other IITs as suitable opportunities present in Europe. We believe IITs will serve to build clinical experience at key cancer centers and will help support efforts to obtain full reimbursement in Europe.

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European Clinical Data Generation

On April 2, 2015, we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable supportive data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

Recent Data Presentations

In March 2018, we announced that a comparative summary of research was presented by Dr. Jonathan Zager of Moffitt Cancer Center in Tampa, FL, at the Society of Surgical Oncology (SSO) annual meeting. In a presentation entitled Percutaneous Hepatic Perfusion (PHP) in Hepatic Liver Metastases, Dr. Zager compared the results from the Company s prior Phase 3 study, published by Hughes, et al (Annals of Surgical Oncology, 2015) with more recent results published by Karydis, et al (Journal of Surgical Oncology, 2017) and Abbott, et al (American Journal of Clinical Oncology, 2017). The Hughes study was conducted from 2005 to 2010, and used an earlier generation of the Melphalan/HDS system, whereas the Karydis and Abbott studies evaluated patients primarily treated with the Generation Two version of the Melphalan/HDS system along with other refinements to the peri- and post-procedure management of patients.

In his presentation, Dr. Zager highlighted that in all three studies results with PHP provided evidence of improved efficacy, with Hughes showing a 5x increase in hPFS over the study control arm (PHP 245 days vs BAC 49 days), and Abbott showing significantly longer hPFS for PHP than treatment with chemoembolization (CE) and Yttrium-90 beads (Y90) (PHP 310 days, CE 80 days, Y-90 54 days). Karydis showed an overall response rate with PHP of 47%, a >84% disease control rate and hPFS of 9.1 months. Regarding safety, Dr. Zager compared select safety data in the Hughes study conducted with the generation one system with data from the Karydis study conducted primarily in patients treated with the generation two system. The Hughes study was characterized by high percentages of hematologic side effects ranging from 60%-86% (anemia, thrombocytopenia, neutropenia). In the Karydis study, Grade 3 and 4 hematologic side effects (anemia, neutropenia, thrombocytopenia) were seen in approximately 30% of patients treated with PHP. Dr. Zager attributed this improvement in the safety profile to improvements in filtration with the generation two system, improved peri- and post-procedure management of patients, and greater experience in the treating centers. Dr. Zager concluded that PHP Therapy can be administered safely in high-volume cancer centers.

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

Patients in the study were treated at the two centers between December 2008 and October 2016. Patients received up to four PHP treatments at UHS and up to six PHP treatments at Moffitt. All patients received at least one PHP treatment, the median number of treatments per patient was two, and a total of 134 PHP treatments had been

administered. Results showed that of the 51 treated patients, 22 (43.1%) showed a partial response, 3 (5.9%) showed a complete response, and 17 (33.3%) had stable disease. The six-month overall and hepatic disease control rates were 64.7% and 70.6% respectively. Survival analysis showed median overall survival of 15.3 months at the time of data cut off. One year overall survival was 64.6%.

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

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

In September 2017, we announced that results of a single institution study were presented at the Cardiology and Interventional Radiology of Europe (CIRSE) annual meeting, held in Copenhagen, Denmark on September 16-20, 2017.

The study, *Prospective Clinical and Pharmacological Evaluation of the Delcath System s Second Generation (GEN2) Hemofiltration System in Patients Undergoing Percutaneous Hepatic Perfusion (PHP) with Melphalan,* was conducted by a team at the Leiden University Medical Center (LUMC) in Leiden, The Netherlands and presented by T.S. Meijer, MD. The study prospectively evaluated filtration efficiency and hematologic side effects in seven patients who received a total of ten PHP procedures with the GEN2 CHEMOSAT system. Pharmacokinetic sampling was conducted at several points during the PHP procedure, and filtration efficiency was calculated at several discrete points. Blood tests were conducted following each procedure to determine hematologic side effect Grade Levels until the blood values normalized.

Results of the study showed the GEN2 CHEMOSAT system had an overall efficiency of 86%, with efficiency highest at the time of highest concentration of melphalan in the blood and declining as melphalan blood concentration declined. Peak efficiency was 95.4% in samples taken after 10 minutes of filtration, 85.9% at the end of the drug infusion period, and 77.5% at the end of the saline washout period. Researchers noted these results were superior to and more consistent than prior experience published with the first generation CHEMOSAT system. Hematologic side effects were mainly Grade 1 and 2 with some Grade 3 and 4 side effects emerging post-procedure, including 40% of treatment cycles showing Grade 4 thrombocytopenia, 80% showing Grade 3 or 4 leucopenia, and 70% showing lymphocytopenia. All patients were asymptomatic and all lab results normalized in three weeks. Other adverse events were managed, and there was no mortality, no severe bleeding complications, and no hypotensive cardiac or cerebral events. Researchers concluded that the GEN2 CHEMOSAT system appears to have higher melphalan filter efficiency, more consistent performance, and appears safe but needs further validation.

In July 2017, the *Journal of Cancer Research and Clinical Oncology* published an analysis of clinical findings from 29 Hannover Medical School patients who were treated with percutaneous hepatic perfusion (PHP®) therapy with Melphalan/HDS as last-line therapy for primary and secondary liver tumors. Hannover Medical School physicians treated 29 patients with a total of 54 PHP procedures. Patients received as many as five treatments each, with an average of two per patient. Nineteen patients were diagnosed with unresectable liver metastases that arose from solid tumors, including 11 cases of ocular melanoma, and the remaining 10 patients had hepatocellular or cholangiocarcinoma.

Across all patients, the overall response rate (ORR) was 19.2 percent, with ocular melanoma patients experiencing the highest ORR (33.3 percent). As has been published previously, high tumor volumes negatively impact overall survival

(OS). Median OS was 261 days for the entire patient group. Two patients with cholangiocarcinoma and one patient with ocular melanoma had the longest survival with 566, 465, and 477 days respectively. Overall, PHP with Melphalan/HDS was well tolerated. Complications including thrombocytopenia, cardiovascular events, ulcerous bleeding, and edema were reported. These results are summarized in the Journal of Cancer Research and Clinical Oncology article, *Safety and Efficacy of Chemosaturation in Patients with Primary and Secondary Liver Tumors.*

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

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

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

Market Access and Commercial Clinical Adoption

Europe

Our market access and clinical adoptions efforts are focused on the key target markets of Germany, United Kingdom and the Netherlands, which represent a majority of the total potential liver cancer market (primary and metastatic) in Europe and where progress in securing reimbursement for CHEMOSAT treatments offers the best near-term opportunities. We also continue to support clinical adoption of CHEMOSAT in Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since launching CHEMOSAT in Europe, over 500 treatments have been performed at over 25 leading European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine. In 2017, SPIRE Southampton Hospital in the U.K. and the Medical University of Hannover in Germany each surpassed 100 treatments with CHEMOSAT since initiating procedures. In 2017, we announced our first patient to receive eight CHEMOSAT treatments, and have seen the average number of repeat treatments performed on a per patient basis consistently increase.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement

codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

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Germany

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

In May 2018 we announced that the German Guidelines Program in Oncology (GGPO) included treatment with Delcath s CHEMOSAT® in the German national treatment guidelines for liver metastases from melanoma. This inclusion of treatment with CHEMOSAT is in the S3 Guidelines, which represents the highest level within the classification of the guidelines indicating that it is based on evidence and consensus within the German clinical community.

The GGPO s update was based on its evaluation of published data on treatment with CHEMOSAT as a loco-regional treatment for melanoma liver metastases. Following this evaluation, and after soliciting additional feedback from the oncology community in Germany, treatment with CHEMOSAT was classified with Evidence Level 1B, indicating the second highest level of evidence. Treatment with CHEMOSAT is the sole therapy classified with this top designation. Other loco-regional therapies previously included in the guidelines have been designated with Evidence Level 4, indicating an absence of clinical trial supporting evidence.

United Kingdom

In May 2014, NICE, a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. Delcath expects to consult again with the Interventional Procedures Advisory Committee at the National Institute for Clinical Excellence (NICE) in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. This would enable greater scope for commercialization because it would allow more use by NHS clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement with the NHS.

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

Netherlands

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

Spain

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

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Turkey

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

Distribution Partners

As a result of the Company s strategy to prioritize resources on the key direct markets of Germany, the Netherlands and the United Kingdom, the Company expects that its distribution strategy will play a lesser role in its current commercial activities. In Spain, the Company has determined that there was no benefit to continuing with an indirect model and therefore terminated its relationship with its distributor in Spain and is now represented in Spain through a sales agency. The Company is represented in Turkey through a distribution partner.

Regulatory Status

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;

completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;

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performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;

submission to the FDA of an NDA after completion of all pivotal clinical trials;

a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and

FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

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

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

Clinical Trials

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

Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.

Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

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

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

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA s goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter (CRL) if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy (REMS) that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the FFDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA s findings of safety and effectiveness for previously approved products. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

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Orphan Drug Exclusivity

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

The FDA has granted Delcath six orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. In October 2013, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of HCC. In July 2015, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of cholangiocarcinoma, which includes ICC.

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

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds rights in eight U.S. utility patents, one U.S. design patent, five pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validation of a European patent directed to our filter apparatus in eight European countries, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications. In July 2017, a patent directed to our chemotherapy filtration system was issued by the U.S. Patent and Trademark Office.

When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT and Melphalan/HDS that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as beyond the treatment of cancers in the liver.

There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

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To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

In certain circumstances, United States patent law allows for the extension of a patent s duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted Delcath five orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, the Company believes that it will provide us with added protection once commercialization of an orphan drug designated product begins.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against Delcath, the Company may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, Delcath plans to enforce its intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
7,022,097	Method For Treating Glandular Diseases and Malignancies	4/4/2006	Owned	6/24/2023
9,707,331	Apparatus For Removing Chemotherapy Compounds from Blood	7/18/2017	Owned	9/17/2034
D708749	Dual Filter	7/8/2014	Owned	7/8/2028
9,314,561	Filter and Frame Apparatus and Method of Use	4/19/2016	Owned	2/7/2034
9,541,544	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	1/10/2017	Owned	8/28/2033
8,679,057	Recovery Catheter Assembly	3/25/2014	Licensed	3/4/2031
9,265,914	Recovery Catheter Assembly	2/23/2016	Licensed	4/5/2031
9,108,029	Recovery Catheter Assembly and Method	8/18/2015	Licensed	2/9/2034
9,814,823	Recovery Catheter Assembly and Method	10/9/2017	Licensed	7/27/2032

Patent Applications in the United States

Application No.	Application Title	Filing	Owned or

		Date	Licensed
15/651,141	Apparatus For Removing Chemotherapy Compounds from Blood	7/17/2017	Owned
15/071,896	Filter and Frame Apparatus and Method of Use	3/16/2016	Owned
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/8/2016	Owned
14/995,677	Recovery Catheter Assembly	1/14/2016	Licensed
14/797,108	Recovery Catheter Assembly and Method	7/11/2015	Licensed
15/728,296	Recovery Catheter Assembly and Method	10/9/2017	Licensed

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Foreign Patents

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
84.098	Dual Filter (Argentina)	6/29/2012	Owned	6/29/2027
343454	Dual Filter (Australia)	7/23/2012	Owned	6/25/2022
146201	Dual Filter (Canada)	5/15/2013	Owned	5/15/2023
ZL 201230277905.5	Dual Filter (China)	3/20/2013	Owned	6/22/2022
1333173	Dual Filter (Europe)	6/27/2012	Owned	6/25/2037
1456186	Dual Filter Cartridge for Fluid Filtration (Japan)	10/26/2012	Owned	10/26/2032
2797644	Filter and Frame Apparatus and Method of Use (Belgium)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (France)	4/12/2017	Owned	12/29/2032
602012031191.6	Filter and Frame Apparatus and Method of Use (Germany)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Great Britain)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Ireland)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Italy)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Luxembourg)	4/12/2017	Owned	12/29/2032

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain

that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there

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are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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

European Regulatory Environment

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

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system

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

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product s design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical

Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the

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manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body s assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer s behalf with regard to the manufacturer s obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the EU must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer s investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can

result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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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 (MDR) which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution and post marketing evaluation.

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

Other International Regulations

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

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of continued economic weakness, which is affecting healthcare budgets and reimbursement.

The CHEMOSAT and Melphalan/HDS competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In the disease states we are targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.

For ICC, gemcitabine plus cisplatin remains the standard of care for the treatment of ICC in patients who are not candidates for surgery.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar , GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib

in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST , GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K

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mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy , Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf , Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease. Many of these treatments are approved in Europe and other global markets.

Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials, regulatory, manufacturing and commercialization capabilities. Our competitors may develop alternative treatment methods, or achieve earlier product development, in which case the likelihood of us achieving meaningful revenues or profitability will be substantially reduced.

Manufacturing and Quality Assurance

We manufacture certain components including our proprietary filter media, and assemble and package the CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. Delcath currently utilizes third-parties to manufacture some components of the CHEMOSAT and Melphalan/HDS. The CHEMOSAT and Melphalan/HDS and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process.

We are committed to providing high quality products to our customers. To honor this commitment, Delcath has implemented updated quality systems throughout our organization. Delcath s quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. These systems are designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization (ISO) with respect to products sold in the EEA. The Company is required to maintain ISO 13485 certification for medical devices to be sold in the EEA, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. On February 17, 2011, we announced that we had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, we announced that we had achieved ISO 13485 certification for our Galway, Ireland facility. All Delcath facilities are presently ISO 13485:2016 certified.

Employees

During 2017, Delcath added 7 employees to support clinical trial implementations in the EU and United States and to meet the demands of commercial sales. As of December 31, 2017, Delcath had 46 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

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Directors, Executive Officers, and Corporate Governance.

Information About Directors. The following table sets forth certain information about our director who successfully stood for re-election and about our directors whose terms will continue after the Annual Meeting.

Name	Age	Position with Delcath	Director Since
Class I Directors Term expiring at the 2019 Annual Meeting			
William D. Rueckert	65	Director	2014
Marco Taglietti, M.D.	58	Director	2014
Class III Directors Terms expiring at the 2018 Annual Meeting			
Simon Pedder, Ph.D.	57	Director	2017
Roger G. Stoll, Ph.D.	74	Chairman	2008
Jennifer K. Simpson, Ph.D.	49	Director	2015

Simon Pedder, PhD. Dr. Pedder currently serves as Chief Business and Strategy Officer at Athenex, Inc., a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer, a company with which he has been an officer since February 2016. During his long career in drug development, Dr. Pedder has held several leadership positions including President and CEO of Cellectar Biosciences from April 2014 to June 2015, President and CEO of Chelsea Therapeutics from May 2004 to July 2012 and previously, Executive Officer and Vice President of Oncology Pharma Business at Hoffmann-LaRoche, Life Cycle Leader and Global Project Leader of Pegasys/IFN and Head of the Hepatitis Franchise at Hoffmann-LaRoche.

Dr. Pedder led the late stage development and commercial launch of multiple proprietary pharmaceutical products, including Pegasys®, Copegus® and Northera®, which will benefit Delcath as it moves through its phase III clinical trials and NDA submission for the Ocular Melanoma and Intrahepatic Cholangiocarcinoma indications. The Board of Delcath has determined that Dr. Pedder is a key addition due to his expertise in late stage drug development.

Dr. Pedder received his Ph.D. in Pharmacology from the College of Medicine at the University of Saskatchewan in Canada, where he was a faculty member in the Department of Pharmacology at the College of Medicine. Dr. Simon earned a Master of Science in Toxicology from Concordia University in Montreal, Canada, a Bachelor of Science in Environmental Studies from the University of Waterloo in Canada and completed the Roche-sponsored Pharmaceutical Executive Management Program at Columbia Business School in New York City

William D. Rueckert was appointed as a Director in December 2014. Mr. Rueckert has served on many public and private corporate boards in both the life science and banking industries. He is currently President of Oyster Management Group, LLC, an investment partnership specializing in community banking. From 2007 until 2012 he served on the board of Novogen Ltd. (ASX, NASDAQ) a biotechnology company based in Sydney, Australia. He acted as Chairman from 2010 until 2012, and as acting CEO led the restructuring of the company, spinning off its major subsidiary, Marshall Edwards, Inc. (now MEI Pharma, Inc. NASDAQ.) He is currently a director of MEI Pharma, Inc. (NASDAQ), a San Diego based company that is developing novel oncology therapies. Until its sale to H. Lundbeck A/S, he was a director of Chelsea Therapeutics International, Ltd. (NASDAQ) whose drug candidate, Northera, was approved by the FDA in 2014. He has also served on the boards of several banks including Westport Bank and Trust, Lafayette American Bank and Hudson United Bank (all NASDAQ.) He currently serves on the board of Fairfield County Bank, a mutually owned, community bank based in Ridgefield, Connecticut, and Bleachers, Inc., a privately held company that streams live and archived sports and entertainment events from independent schools. Among his civic associations, Mr. Rueckert is a Director and President of the Cleveland H. Dodge Foundation,

Co-Chairman of the Board of Trustees of Teachers College, Columbia University, a Director of the Y Retirement Fund, a Trustee of International House, an Emeritus Director of the YMCA of Greater New York, a Trustee of the American University of Beirut and a

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Director of Wave Hill, Inc. He earned a BA in Spanish in 1977 from the University of New Hampshire. The Nominating Committee considered Mr. Rueckert s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Mr. Rueckert should serve as director of Delcath.

Roger G. Stoll, Ph.D. was appointed as a Director in December 2008, Executive Chairman in September 2014 and has served as our Chairman since October 1, 2015. From 2002 to 2008, he served as Chairman, Chief Executive Officer and President of Cortex Pharmaceuticals, Inc. (OTCBB: CORX). In August 2008, he was appointed Executive Chairman of its board. He retired from Cortex Pharmaceuticals in August, 2012. From 2001 to 2002, he was a consultant to several east coast venture capital firms and startup ventures. From 1998 to 2001, he was Executive Vice President of Fresenius Medical Care-North America, in charge of the dialysis products division and the diagnostic systems business units, which included hemodialysis machines and dialysis filters equipment. From 1991 to 1998, Dr. Stoll was Chief Executive of Ohmeda, a global leader in anesthetic agents, critical care drugs and related operating room equipment and devices. He also served on the boards of directors of St. Jude Medical and the BOC Group, plc. From 1986 to 1991, Dr. Stoll held several executive management positions at Bayer, AG, including Executive Vice-President and General Manager for its worldwide Diagnostic Business Group. Prior to that, Dr. Stoll worked for American Hospital Supply Corp., where he rose from Director of Clinical Pharmacology to President of its American Critical Care Division. He began his pharmaceutical career at the Upjohn Company in 1972. Dr. Stoll obtained his B.S. in Pharmacy from Ferris State University, obtained a Ph.D. in Biopharmaceutics and Drug Metabolism at the University of Connecticut and was a post-doctoral fellow for two years at the University of Michigan. From 2008 and until its sale to H. Lundbeck A/S, Dr. Stoll served on the board of directors of Chelsea Therapeutics (NASDAQ: CHTP) and was a member of that board s audit and compensation committees. Dr. Stoll in the past also served on the boards of Questcor and Agensys, HIMA and PMA (now PhRMA). Dr. Stoll also serves on the School of Pharmacy Advisory Board of the University of Connecticut. The Nominating Committee considered Dr. Stoll s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical and medical device experience, as well as the overall composition of the Board, in making the determination that Dr. Stoll should serve as director of Delcath.

Dr. Marco Taglietti, M.D. was appointed as a Director in December 2014. Dr. Taglietti serves as CEO and on the Board of Directors of NASDAQ-listed SCYNEXIS, Inc., a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives. Prior to its acquisition in February 2014, Dr. Taglietti served as Executive Vice President, Research and Development, and Chief Medical Officer of Forest Laboratories. He also served as President of the Forest Research Institute. Prior to joining Forest Labs in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel after 12 years at Schering-Plough Corporation where he last held the position of Vice President, Worldwide Clinical Research for Anti-Infectives, Oncology, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. He received his medical degree and board certifications from the University of Pavia in Italy. The Nominating Committee considered Dr. Taglietti s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Dr. Taglietti should serve as director of Delcath.

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

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Information About our Executive Officers

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

Name	Age	Office Currently Held
Jennifer K. Simpson, Ph.D.	48	President and Chief Executive Officer
Barbra C. Keck, M.B.A.	39	Chief Financial Officer and Secretary
John Purpura	55	Executive Vice President, Global Head of Operations

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

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

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

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

University of New York at Stony Brook.

Board of Directors. We currently have five directors serving on the Board of Directors. The Board of Directors oversees the business affairs of the Company and monitors the performance of management. In accordance with our corporate governance principles, our Board does not involve itself in day-to-day operations.

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The directors keep themselves informed through discussions with the Chairman of the Board, Roger G. Stoll, Jennifer K. Simpson, in her capacity as Director and Chief Executive Officer, or CEO, and other key executives, and by reading the reports and other materials that management sends them and by participating in Board and committee meetings. Our directors hold office until their successors have been elected and qualified unless the director resigns or is removed or by reason of death or other cause is unable to serve in the capacity of director.

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

Attendance. The Board of Directors met 12 times in 2017 (including regularly scheduled and annual meetings). During 2017, each director attended at least 75% of the aggregate of: (i) the total number of meetings of the Board (held during the period for which he or she served as a director) and (ii) the total number of meetings held by all committees of the Board of Directors on which he or she served (held during the period that he or she served). It is Delcath s policy that, absent unusual or unforeseen circumstances, all directors are expected to attend annual meetings of stockholders, and all of our then directors attended our 2017 Annual Meeting.

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

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

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

Risk Assessment of Compensation Programs. Our Compensation and Stock Option Committee annually evaluates whether our compensation programs encourage excessive risk-taking by employees at the expense of long-term Company value. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in the Delcath 2009 Stock Incentive Plan and the Compensation Committee s role in the consideration and approval of certain awards, the Compensation and Stock Option Committee does not believe that

our compensation programs encourage excessive or inappropriate risk-taking, motivate imprudent risk-taking or create risks that are reasonably likely to have a material adverse effect on the Company.

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Director Continuing Education. We require our directors to attend, at least annually, educational programs provided by various universities, stock exchanges and other regulatory agencies to assist our directors in maintaining or enhancing their skills and abilities as directors and to update their knowledge and understanding of the pharmaceutical, medical device and biopharma industries and the regulatory environment in which Delcath operates and to which it is subject.

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

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

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

The Board has determined that each member of the Audit Committee, William D. Rueckert (Chair), and Simon Pedder and Roger Stoll qualifies as an audit committee financial expert as defined by SEC rules. During 2017, the Audit Committee met four times. Each member of the Audit Committee is independent within the meaning of the NASDAQ listing rules and otherwise meets the financial statement proficiency requirements of the NASDAQ listing rules. The Audit Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

Compensation and Stock Option Committee. The Compensation and Stock Option Committee (the Compensation Committee) assists the Board of Directors in the discharge of the Board s responsibilities with respect to the compensation of Delcath s directors, executive officers, and other key employees and consultants. The Compensation Committee establishes our overall compensation philosophy and is authorized to approve the compensation payable to our executive officers, including our named executive officers, and other key employees, including all perquisites, equity incentive awards, cash bonuses, and severance packages. The Compensation Committee also administers certain of our employee benefit plans, including its equity incentive plans, and is responsible for assessing the independence of compensation consultants and legal advisors. The Compensation Committee has concluded that each of Wexler, Burkhart, Hirschberg & Unger, LLP, outside legal counsel to the Compensation Committee and the Company, as well as Pearl Meyer & Partners, compensation consultant to the Compensation Committee, qualified as

independent. The Compensation Committee exercises sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements. The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert, Simon Pedder and Roger Stoll, each of whom is independent within the meaning of the NASDAQ listing rules. During 2017, the Compensation and Stock Option Committee met nine times. The Compensation and Stock Option Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

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

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

The current members of the Nominating Committee are Roger Stoll (Chairman), William D. Rueckert and Marco Taglietti, each of whom is independent, within the meaning of the NASDAQ listing rules. During 2017, the Nominating Committee met one time. The Nominating Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

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

Recommendations by Stockholders of Director Nominees. The Nominating Committee will consider any recommendation by a stockholder of a candidate for nomination as a director. If a stockholder wants to recommend a director candidate for consideration by the Nominating Committee, the stockholder should submit the name of the proposed nominee, together with the reasons why the stockholder believes the election of the candidate would be beneficial to the Company and its stockholders and the information about the nominee that would be required in a proxy statement requesting proxies to vote in favor of the candidate. The stockholder s submission must be accompanied by the written consent of the proposed nominee to being nominated by the Board and the candidate s agreement to serve if nominated and elected. Any such submission should be directed to the Nominating Committee at Delcath s principal office, 1633 Broadway, Suite 22C, New York, New York 10019. If a stockholder intends to nominate a person for election to the Board of Directors at an annual meeting, the stockholder must provide Delcath with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in Delcath s proxy statement for such meeting (as described below under the heading Stockholder Proposals For the 2018 Annual Meeting) and must otherwise comply with our amended and restated certificate of incorporation. Copies of any recommendation received in accordance with these procedures will be distributed to each member of the Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

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

material that is unduly hostile, threatening, illegal or similarly unsuitable.

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Code of Ethics. We maintain a Code of Business Conduct and Ethics (Code) that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including our independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates our expectations of our employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of our Code is published on our web site at http://delcath.com/investors/governance. We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer or principal accounting officer and persons performing similar functions on our web site.

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REPORT OF THE AUDIT COMMITTEE

The Audit Committee reviewed and discussed the Company s audited financial statements for the fiscal year ended December 31, 2017, with management and Grant Thornton, the Company s independent registered public accounting firm for the fiscal year ended December 31, 2017. The Audit Committee also discussed with Grant Thornton the matters required to be discussed by the Statement on Auditing Standards No. 16, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T regarding Communication with Audit Committees. The Audit Committee has received and reviewed the written disclosures and the letter from Grant Thornton required by applicable requirements of the Public Company Accounting Oversight Board regarding Grant Thornton s communications with the Audit Committee concerning independence, and has discussed with Grant Thornton its independence from the Company.

Based on the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company s audited financial statements be included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, for filing with the Securities and Exchange Commission.

Submitted by the Audit Committee of the Board of Directors,

William Rueckert (Chair)

March 16, 2018

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SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who are beneficial owners of more than 10% of our common stock to file with the Securities and Exchange Commission reports of holdings and changes in beneficial ownership of Delcath s equity securities. Based on a review of copies of reports furnished to Delcath or written representations that no reports were required, we believe that all reports were timely filed in 2017.

Delcath maintains a Code of Business Conduct and Ethics (Code) that applies to all employees, including its principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including its independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates Delcath s expectations of its employees that enable the Company to provide accurate and timely disclosure in its filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of the Company s Code is published on its web site at http://delcath.com/investors/governance and is incorporated by reference herein. The Company intends to disclose future amendments to certain provisions of its Code, or waivers of such provisions granted to its principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions on its web site. Except as expressly stated herein, the information contained on Delcath s website does not constitute a part of this Annual Report on Form 10-K and is not incorporated by reference herein.

Executive Compensation.

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

Our Compensation Committee engaged an independent compensation consulting firm, Pearl Meyer, to assist with the formulation of our executive compensation programs for 2017.

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

Base Salary. We pay our executive officers a base salary, which our Compensation Committee reviews and determines annually. Base salaries are used to compensate our executive officers for performing the core responsibilities of their positions and to provide them with a level of security with respect to a portion of their total compensation. Base salaries are set in part based on the executive s unique skills, experience and expected contribution to the Company, as well as individual performance, including the impact of such

performance on our business results, and the period of the executive s performance. Decisions regarding base salary increases take into account the executive s current base salary, third-party benchmark and survey data, and the salary compensation paid to executive officers within and outside the Company, as well as the Company s overall performance, its ability to afford such increases, its success in achieving its operational and strategic goals and objectives, and the executive officer s contribution to Company performance.

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Annual Incentive Cash Awards. Annual incentive compensation is intended to establish a direct correlation between annual cash awards and the performance of the Company. The Company s Annual Incentive Plan (AIP) is an annual incentive cash bonus plan designed to align the interests of participants with the interests of the Company and its stockholders. The AIP is designed to strengthen the link between a participant s pay and his or her overall performance and the Company s performance, focus participants on critical individual and corporate objectives, offer a competitive cash incentive, and encourage and reward performance and competencies critical to the Company s success.

Long-Term Incentive Compensation. In addition to using base salaries and annual incentive cash bonuses, which our Compensation and Stock Option Committee views as short-term compensation, a portion of our executive compensation is in the form of long-term equity compensation. Our Long-Term Incentive Plan (LTIP) is an annual equity-based incentive plan designed to align participants interests with those of the Company and its stockholders by rewarding participants for their contributions to the long-term success of the Company. The LTIP is designed to incentivize Company leaders to focus on the long-term performance of the Company, offer participants competitive, market-based long-term incentive award opportunities, and strengthen the link between a participant s compensation and his or her overall performance and the Company s overall long-term performance. We believe the LTIP assists us in achieving an appropriate balance between our short- and long-term.

Interface of Executive Officers with Compensation Committee in Determining Compensation. The Compensation Committee, based on input from the Company s Chief Executive Officer and Chairman, determines the compensation of our executive officers. The CEO and Chairman assist the Compensation Committee by providing performance assessments and compensation recommendations for each of the Company s executive officers, including the named executive officers (other than the CEO). The final decisions regarding the compensation for the named executive officers is then independently assessed and approved by the Compensation Committee. Other than completing a self-evaluation performance review, and submitting it to the Compensation Committee, the CEO does not participate in the formulation or discussion of her compensation. The Chairman provides the performance review for the CEO and submits that review to the Compensation Committee for its consideration. The Chairman also has discussions with the full committee related to all the performance items submitted for the named executive officers. Upon completion of these reviews, final decisions related to the compensation of the CEO require approval of the full Board of Directors after recommendations are made by the Compensation Committee.

Role of Compensation Consultants. The Compensation Committee retained PM&P as its independent compensation consultant to assist the Compensation Committee in evaluating executive compensation programs. PM&P reports directly to the Compensation Committee, and is not permitted to perform services for management unless approved by the Compensation Committee.

Inputs to Committee Decision Making.

Performance Evaluation Process. The Company utilizes a formal annual performance review program to evaluate our executives competencies, as well as individual performance objectives. The competencies in the program include: commitment to quality, integrity and ethics, as well as results oriented, teamwork, dependability, job knowledge and productivity. Each executive performs a self-evaluation and also is rated by the CEO on his or her competencies at year end and a final average total rating is calculated. Corporate performance objectives, which are set at the beginning of the year, are linked to the Company s overall performance and attainment of these objectives. Following completion of the performance year, the CEO submits performance evaluations and recommendations for each executive to the Executive Chairman who after review with the CEO then submits information to the Compensation Committee. The Committee reviews the completed individual performance evaluation forms for our executive officers

including the CEO and assesses the Company s overall performance relative to the achievement of corporate objectives. The information gathered as part of this evaluation process was used by our Compensation Committee to assist it in making compensation decisions.

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While the Company conducts its performance evaluations annually, the 2017 AIP was based solely on the achievement of corporate performance goals.

Peer Group Review. The Compensation Committee, with the assistance of PM&P, generally reviews the peer group on a regular basis. Due to the unique nature of the Company s business, we continually face challenges as we strive to develop the most appropriate mix of companies to comprise our peer group. The challenges we face include:

- We are an early commercial stage company with limited product revenues ($1.1M in 2014). As a result, a typical revenue range for peer selection purposes is more challenging due to our relatively small size.

- We are a medical device company and specialty pharmaceutical company. Our proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our CHEMOSAT System for Melphalan is classified as a class IIb medical device and has been approved in Europe. In the United States, we are considered a drug device combination product regulated under a 505(b)(2) new drug application which is not currently approved yet. (As previously discussed, we received a complete response letter from the U.S. FDA to our NDA.) Because our product is regulated as both a device and a drug in the U.S. only, we have to recruit executive talent who have background and skill sets from both industries and who have experience in both device and drug development from larger, more established companies.

- There are very few peers across the medical device and pharmaceutical industries with a similar combination product which is considered a drug in certain regions and classified as a device in other regions, and so exact peers for us are difficult to identify.

Generally, the Compensation Committee considers each of the above challenges as well as the following selection criteria to select its peer group:

- We focused on companies with industry/product similarity Drug Delivery Systems/Medical Device companies with a focus on cancer/oncology and Pharmaceuticals/Biopharmaceuticals/Biotherapeutics companies with a cancer focused drug. As a result, multiple GICS sub-industries were reviewed and considered.

- We used a range of revenue from $0 $100M to develop a pool of potential firms to consider.

- We then narrowed the pool of potential companies based on market capitalization and other secondary factors (R&D expenses, number of employees, further test of business model and product similarity, etc.).

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Due to the changes in the Company s size and market capitalization, the Compensation Committee believed that a re-assessment of the peer group was warranted in 2014. The Compensation Committee, the Chairman, and management worked with PM&P to revise the peer group to reflect the smaller size of Delcath and the increased intensity in the clinical development activities. The following table reflects the new peer group which was reviewed and approved by the Compensation Committee and the full board of Delcath before being implemented:

Company	Industry[1]	Revenue[2]	Market Capitalization[3]
Accurexa Inc.	Healthcare Equipment	$ 0	$ 17
Adamis Pharmaceuticals Corporation	Pharmaceuticals	$ 0	$ 49
Aethlon Medical, Inc.	Healthcare Equipment	$ 1	$ 33
Arno Therapeutics, Inc.	Biotechnology	$ 0	$ 27
ArQule Inc.	Biotechnology	$ 11	$ 71
BSD Medical Corp.	Healthcare Equipment	$ 5	$ 23
Celator Pharmaceuticals, Inc.	Biotechnology	$ 0	$ 65
Cellectar Biosciences, Inc.	Biotechnology	$ 0	$ 16
Celsion Corp.	Biotechnology	$ 1	$ 59
Champions Oncology, Inc.	Life Sciences Tools and Services	$ 10	$ 46
Cytosorbents Corporation	Healthcare Equipment	$ 4	$ 70
Emisphere Technologies, Inc.	Pharmaceuticals	$ 0	$ 23
MetaStat, Inc.	Life Sciences Tools and Services	$ 0	$ 20
Nephros, Inc.	Healthcare Equipment	$ 2	$ 19
OncoGenex Pharmaceuticals, Inc.	Biotechnology	$ 35	$ 59
Median		**$ 1**	**$ 33**
Delcath Systems Inc.	**Health Care Equipment**	**$ 1**	**$ 19**

(1) Reflects the sub-industry as defined under Global Industry Classification Standard.
(2) Data from S&P Capital IQ database, as of most recent quarter end at the time the analysis was completed (October 2014).
(3) Data from S&P Capital IQ database, as of most recent month end at the time the analysis was completed (October 2014).

The Committee believes this peer group continues to represent a reasonable mix of companies to appropriately address the concerns presented above and currently reflects the size and business model of our Company.

Benchmark Analyses. The Compensation Committee reviews our executive officers overall compensation packages in 2017. The analysis includes a review of total target compensation for each executive officer as well as for each component of compensation, relative to executives in comparable positions or with comparable roles.

The Compensation Committee generally targets around the median percentile range of the competitive market for the various elements of compensation, yet individual executives may be paid above or below this point depending upon, among other factors, the skills and experience, tenure in the position, overall individual performance and additional responsibilities of the executive. In addition to evaluating the peer group data, the Compensation Committee also uses survey data for a broader pharmaceutical, medical device and biopharma industry perspective. Overall, the Compensation Committee attempts to maintain individual compensation within competitive ranges, with some exceptions based on prior experience and compensation history for each individual.

Pay Mix. The Compensation Committee seeks to achieve executive compensation objectives through the use of a mix of compensation elements for each executive officer. While the Compensation Committee generally strives to award a significant amount of each NEO s target total direct pay opportunity in the form of variable, rather than fixed compensation, it does not have rigid guidelines or formulas in determining the amount and mix of compensation elements for each executive officer.

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Base Salary. Effective February 2017, Barbra Keck, previously the Senior Vice President of Finance, Principal Accounting Officer and Principal Financial Officer of the Company, became the Chief Financial Officer of the Company. In connection with her promotion to Chief Financial Officer, Ms. Keck s annual base salary was increased from $247,200 in 2016 to $300,000 in 2017.

The following table summarizes the amount of base salary and year-over-year increase for each of our named executive officers for 2016 and 2017.

Executive	Hire Date	2015 Base Salary	Percent Increase in 2016	2016 Base Salary	Percent Increase in 2017	2017 Base Salary
Jennifer K. Simpson, Ph.D.	3/23/2012	$ 427,000	3.0%	$ 439,810	3.0%	$ 453,004
Barbra C. Keck, M.B.A.	1/5/2009	$ 240,000	3.0%	$ 247,200	21.4%	$ 300,000
John Purpura, M.S.	11/16/2009	$ 270,569	13.5%	$ 307,000	3.0%	$ 316,210

Annual Incentive Plan. Under the AIP, annual incentive target award opportunities are expressed as a percentage of a participant s actual base salary for the performance year, beginning January 1. The following table sets forth, for each executive, the applicable target bonus percentage of base salary to which each executive could have been entitled, as well as the actual bonus earned based on company performance in 2017:

	Target Incentive Bonus Opportunity		2017 Incentive Award Earned	
Executive	Target Bonus Expressed as % of Base Salary	Dollars ($)	Actual Payout as a % of Target Bonus	Dollars ($)
Jennifer K. Simpson, Ph.D.	50.0%	$ 226,502	65.0%(1)	$ 147,226(1)
Barbra C. Keck, M.B.A.	35.0%	$ 105,000	65.0%(1)	$ 68,250(1)
John Purpura, M.S.	45.0%	$ 142,295	65.0%(1)	$ 92,491(1)

(1) Amounts determined as of the date of filing this Amendment No. 1 but have not yet been paid.

For 2017, AIP goals were based entirely on Company performance to focus all the executives on the same critical challenges facing the Company.

Company performance in 2017 has been measured based upon achievement of objectives in the following areas: (1) Clinical Trials; (2) Capital; and (3) Sales.

Actual 2017 corporate performance, including assigned weighting and actual achievement in each area is still undergoing assessment by our Compensation Committee.

Long Term Incentive Plan. Grants under the LTIP are typically comprised of a mix of restricted stock and stock option awards granted in the first quarter of each year with the number of shares subject to the awards designed to deliver a

competitive value targeted at the mid-market of the executive compensation comparison group. These guidelines are reviewed periodically based on prevailing compensation comparison group levels, however, and the Compensation and Stock Option Committee then uses these guidelines to determine long-term equity incentive awards for our named executive officers based upon a holistic assessment of Company and individual performance for the prior year and its view of the appropriate incentives to best help achieve the Company s business objectives. Our ability to provide awards at the mid-market level has been difficult to do in the past few years due to share availability. Such awards in the past few years have typically been at or below the market 25th percentile.

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There were no long-term equity awards to our named executive officers in 2017. Due to the lack of available shares for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2017 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

Employment Agreements, Executive Security Agreements and Confidentiality and Restrictive Covenant Agreements.

Executive Security Agreements. In early 2017, Dr. Simpson, Ms. Keck and Mr. Purpura (the Executives) each executed an Executive Security Agreement (Executive Agreements) with the Company. Each executive is employed at will . The Executive Agreements provide for the payment of severance to each of the Executives upon a qualifying termination (a termination which is involuntary but not for cause or a termination for good reason as defined in their employment agreements with the Company) to be paid within 10 days of such event as follows: (i) all base salary owed to the date of the qualifying event, (ii) a one-time lump sum fee equal to the Executive s monthly base salary for a term of two years for Jennifer Simpson and 18 months for Barbra Keck and John Purpura, and (iii) COBRA payments should the Executive remain on the Company s health benefit plans. The Executive would also be entitled to any annual incentive payments due by March 15th of the following year. The term of the Executive Agreements continues until terminated by mutual agreement of each Executive and the Company.

Additional Benefits; 401(k) Plan. All salaried employees participate in a variety of retirement, health and welfare, and paid time-off benefits designed to enable the Company to attract and retain a talented workforce in a competitive marketplace. These benefits and related plans help ensure that the Company has a productive and focused workforce. The Company utilizes a 401(k) savings plan to enable employees to plan and save for retirement. The Company does not provide matching contributions.

Other Compensation. As an early commercial stage company, the Company does not have pension or deferred compensation plans or arrangements.

Prohibition on Hedging and Pledging. Pursuant to the Company s insider trading policy, the Company prohibits any director, officer or other employee from hedging or pledging Company securities.

Clawback Policy. We have not yet adopted a formal clawback policy because we await the issuance of clarifying regulations by the SEC regarding required elements of any such clawback policy. As required by Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, we intend to adopt a clawback policy upon issuance by the SEC of final rules regarding clawbacks.

Internal Revenue Code Section 162(m) Considerations. Section 162(m) of the Internal Revenue Code generally denies publicly-held corporations a federal income tax deduction for compensation exceeding $1,000,000 paid to the Chief Executive Officer and each of the three next most highly paid executive officers serving as such at year end, excluding the Chief Financial Officer. While the Compensation Committee takes Section 162(m) into account when determining the type and amount of compensation to provide to the named executive officers, the Compensation Committee may award compensation that is not deductible if it believes it is reasonable and appropriate to do so.

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Summary Compensation Table.

The following table sets forth the total compensation awarded to, earned by or paid to: (i) each person who served as a principal executive officer during 2017, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2017. We refer to these individuals as our named executive officers.

Name & Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[2]	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Jennifer K. Simpson, Ph.D. President and Chief Executive Officer	2017	453,004	147,226[3]	7,476				607,706[3]
	2016	439,810	149,535					589,345
Barbra C. Keck, M.B.A. Chief Financial Officer and Secretary[1]	2017	293,400	68,250[3]	4,788				366,438[3]
	2016	247,200	58,834					306,034
John Purpura, M.S. Executive Vice President Global Head of Operations	2017	316,210	92,491[3]	7,140				415,841[3]
	2016	291,442	93,942					385,384

(1) Effective February 2017, Ms. Barbra C. Keck, previously the Senior Vice President of Finance, Principal Accounting Officer and Principal Financial Officer of the Company, became the Chief Financial Officer of the Company.

(2) Due to the lack of available shares for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2016 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

(3) Amounts determined as of date of filing this Amendment No. 1 but have not yet been paid.

Grants of Plan-Based Awards Table 2017. The following table sets forth grants of plan-based awards made during the fiscal year ended December 31, 2017 to the named executive officers. All equity grants were made pursuant to the 2009 Plan.

Name	Grant Date (equity awards)	Estimated Possible Payouts Under Non-Equity Incentive Plan	Number of Shares (#)	All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and

	Awards Target ($)		**(#)**	**Option Awards**
Jennifer K. Simpson	2/8/2017			$
Barbra C. Keck	2/8/2017			$
John Purpura	2/8/2017			$

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Outstanding Equity Awards at Fiscal Year-End Table 2017.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2017.

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

Options Exercises and Stock Vested Table 2017.

The following table sets forth information relating to the vesting during 2017 of restricted stock awards granted to the named executive officers. No stock options were exercised by the named executive officers during 2017.

Name	Number of shares acquired on vesting (#)	Value realized on vesting ($)
Jennifer K. Simpson	1	262
Barbra C. Keck	1	95
John Purpura	1	131

Potential Payments upon Termination or Change of Control.

The following table shows the potential incremental value transfer to each named executive officer under various termination or change-in-control scenarios as of December 29, 2017, the last business day of 2017. Unvested, unexercised stock options and unvested restricted stock awards are valued at the closing market price of the Company s common stock on that date. The actual amounts to be paid out in respect of the other named executive officers can only be determined at the time of such named executive officer s actual separation from the Company.

Named Executive Officer[1]	Retirement or Voluntary Termination Without Good Reason	Termination for Cause	Involuntary Termination (Termination Without Cause, or Termination for Good Reason)	Upon a Change in Control[1]	Death or Disability Termination
Jennifer K. Simpson				$	
Barbra C. Keck				$	
John Purpura				$	

(1) Upon a change in control, the vesting of all equity incentive awards is accelerated. The amount shown represents the value of restricted stock units held on December 29, 2017, based on the closing trading price of our common stock on that date.

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Director Compensation 2017

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

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

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

Dr. Stoll receives an annual retainer fee as Director and Chairman of the Board of $68,000. Additionally, we reimburse all non-employee directors for their reasonable out-of-pocket travel expenses incurred in attending meetings of our Board of Directors or any committees of the Board. Due to the low number of shares remaining available for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any equity awards to non-employee directors during 2016 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

The following table sets forth the compensation awarded to, earned by or paid to each non-employee director who served on our Board of Directors in 2017.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Harold S. Koplewicz. M.D.[1]	$ 45,333	$	$	$	$ 45,333
Simon Pedder, Ph.D.[2]	$ 7,000	$	$	$	$ 7,000
William D. Rueckert	$ 72,000	$	$	$	$ 72,000
Roger G. Stoll, Ph.D.	$ 68,000	$	$	$	$ 68,000
Marco Taglietti, M.D.	$ 65,000	$	$	$	$ 65,000

(1) Dr. Koplewicz resigned as a director in September 2017.
(2) Dr. Pedder was appointed as a director in November 2017.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following tables contain information regarding the beneficial ownership of our common stock as of August 10, 2018, held by: (i) each of our directors; (ii) each of our named executive officers in the Summary Compensation Table; (iii) all of our directors and executive officers as a group; and (iv) each person or group known by us to own beneficially more than 5% of the outstanding common stock. We are not aware of any 5% or more holders of our Common Stock as of August 10, 2018 except as set forth below. The information set forth in the table below excludes shares issuable upon exercise of our outstanding warrants held by certain investors that are presently exercisable, subject to limitations on exercisability for more than 4.9% or 9.9% of our outstanding shares of common stock, depending upon the particular investor. Except as indicated in the footnotes below, the address of the persons or groups named below is c/o Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019.

Directors and Officers

	Shares Beneficially Owned[1]	
Name of Beneficial Owner:	**Number**	**Percent**
Named Executive Officers and Directors:		
Jennifer K. Simpson, Ph.D.	11	*
John Purpura, M.S.	1	*
Barbra C. Keck, M.B.A.	11	*
Simon Pedder, Ph.D.		*
Roger G. Stoll, Ph.D.	1,001	*
William D. Rueckert	3,209	*
Marco Taglietti, M.D.	1	*
All directors and executive officers as a group (6 people)[9]:	4,234	*

* Less than 1%

(1) Except as indicated in these footnotes: (i) the persons named in this table have sole voting and investment power with respect to all shares of common stock beneficially owned; (ii) the number of shares beneficially owned by each person as of August 10, 2018, includes any vested and unvested shares of restricted stock and any shares of common stock that such person or group has the right to acquire within 60 days of July , 2018, upon the exercise of stock options; and (iii) for each person or group included in the table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the 932,158 shares of common stock outstanding on August 10, 2018, plus the number of shares of common stock that such person or group has the right to acquire within 60 days of August10_, 2018.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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

Transactions with Related Persons. We have adopted a written policy for the review and approval or ratification of transactions between Delcath and Related Parties (as defined below). Under the policy, our Nominating Committee will review the material facts of proposed transactions involving Delcath in which a Related Party will have a direct or

indirect material interest. The Nominating Committee will either approve or disapprove Delcath s entry into the transaction or, if advance approval is not feasible, will consider whether to ratify the transaction. The Nominating Committee may establish guidelines for ongoing transactions with a Related Party, and will review such transactions at least annually. If the aggregate amount of the transaction is expected to be less than $200,000, such approval or ratification may be made by the Chair of the Committee. In determining whether to approve or ratify a transaction with a Related Party, the Nominating Committee (or Chair) will consider, among other factors, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party and the extent of the Related Party s interest in the transaction.

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

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

No related person transactions occurred during 2017.

Compensation Committee Interlocks and Insider Participation. During 2017, Marco Taglietti and William D. Rueckert served as members of our Compensation and Stock Option Committee. None of the current members or members serving during 2017 of the Compensation and Stock Option Committee is a current or former officer or employee of Delcath at the time of their service on the Compensation and Stock Option Committee, nor did any Compensation and Stock Option Committee member engage in any related person transaction that would be required to be disclosed under Item 404 of Regulation S-K. During 2017, none of Delcath s executive officers served on the compensation committee (or equivalent) or on the board of directors of another entity whose executive officers served on the Compensation and Stock Option Committee or our Board of Directors.

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

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

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

Staggered Board of Directors

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

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage

an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

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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 August 11, 2018, we had 932,158 shares of common stock outstanding and no shares of preferred stock outstanding. As of August 11, 2018, we had 25.2 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.76 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.

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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.

Recent Preferred Stock Issuances

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series A Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series A Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series A Preferred Stock). On July 2, 2017, we entered into an exchange agreement (the Exchange) with one of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the Series A Preferred Shares). The Exchange was made in reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Shares were entitled to the whole number of votes equal to $4.2 million divided by $644,000.00 (the closing bid price on June 13, 2016, the date of issuance of the Notes as adjusted for the reverse stock split effected in July 2016,) or 3,761 votes. The Series A Preferred Stock had no dividend, liquidation or other preferential rights to our common stock, and each share of Series A Preferred Stock was redeemed for the amount of $0.001 on August 28, 2017.

On July 11, 2017, we entered into an Amended and Restated Securities Purchase Agreement (the Amended Purchase Agreement) with certain institutional investors for the sale by the Company of 2,360 shares of Series B Preferred Stock (the Series B Preferred Stock) at a purchase price of $1,000 per share, in a private placement. The aggregate gross proceeds for the sale of the Series B Preferred Stock is $2.0 million. The Company intends to use the proceeds from the transaction for general corporate purposes. The restricted shares of Series B Preferred Stock have no registration rights and thus will not be eligible for legend removal for a period of at least six months from the date of closing. This Amended Purchase Agreement amends the July 5, 2017 Securities Purchase Agreement (the Purchase Agreement) into which we entered with certain institutional investors (the Investors) for the sale by the Company of 2,360 shares of Series B Preferred Stock in a registered direct offering. The Series B Preferred Stock shall be entitled to the whole number of votes equal to $2.0 million divided by $32,675.00 (the closing bid price on July 5, 2017, the date of sale of the Series B Preferred Stock), or 30,607 votes. The Series B Preferred Stock has no liquidation or other rights which are preferential to our common stock. The Series B Preferred Stock was redeemed for $2,360,000 in August 2017.

On August 28, 2017, the Company entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the SPA. As of the date the Agreement was entered into, the Investor held $11,444,637 aggregate principal amount of Notes of which there was $10,092,857 aggregate Restricted Principal, (as defined in the Notes) of Notes (the Restricted Notes), secured by such aggregate cash amount held in a collateral account of the Company in the same amount (the Restricted Cash) and (y) $1,351,780 principal of Notes (the Unrestricted Notes), (ii) 4,200 shares of Series A Preferred Stock and (iii) 2,006 shares of Series B Convertible Preferred Stock.

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Pursuant to the Agreement, (a) on the date thereof the Company and the Investor took the following actions (the Initial Restructuring): (i) the Investor released restrictions on $1,650,000 of Restricted Cash (the Initial Release), (ii) the Investor consented to the use of additional Restricted Cash to effect redemptions of the Series A Preferred Shares and the Series B Preferred Shares, (iii) the Investor cancelled $1,200,000 aggregate principal of the Notes (such portion of the Notes, the Cancellation Note), (iv) the Company redeemed all the Series A Preferred Shares outstanding for a cash payment to the Investor of $4.20 and (v) the Company redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 and (b) upon the consummation of a reverse stock split of our Common Stock of at least twenty to one (the Reverse Stock Split Event , and such date, the Reverse Stock Split Date) by September 15, 2017, the Company and the Investor shall have taken the following actions (the Additional Restructuring , and together with the Initial Restructuring, the Restructuring): (i) the Investor shall consent to the use of Restricted Cash to effect redemptions of $4,000,000 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Redemption Notes), (ii) the Company shall redeem the Redemption Notes for a redemption price of $6,436,852.80 (the Redemption Price) and (iii) the Company shall exchange (the Exchange), pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, $2,436,852.80 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Exchange Notes , and together with the Redemption Notes, the Restructured Notes) for new warrants to purchase 114,286 shares of its Common Stock (the New Warrants , as exercised, the New Warrant Shares). The New Warrants expire on the 42 month anniversary of the date of issuance and bear an exercise price of $61,250.00 per share (which shall be adjusted to the new lower purchase price per share if there is a subsequent down round financing). The Investor, in lieu of an exercise of the New Warrants pursuant to a cash payment of the aggregate exercise price of the number of New Warrants being exercised, may exercise the New Warrants, in whole or in part, by electing instead to receive upon such exercise two shares and one hundred and twenty-five thousandths of a share of the Company s Common Stock for each Warrant Share exercised pursuant to this provision. The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act) and Rule 144(d)(3)(ii) of the 1933 Act. As a result of not having effected a reverse stock split by September 15, 2017, the Additional Restructuring did not occur.

Amendment to Restructuring Agreement

As a result of the lack of requisite approval by Delcath stockholders for the Company s proposed reverse stock split, the parties and the two investors in the Notes entered into an amendment to the August restructuring agreement on October 10, 2017 as follows: (i) on the date that the Company effects a reverse split of its common stock, (x) the Company will exchange, pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, an aggregate principal amount of those notes equal to $279,015 for new warrants to purchase an aggregate of 255 shares of Common Stock, and the Company shall redeem all the Series C Preferred Shares then outstanding for a cash payment of $590,000 and (ii) upon the initial consummation, on or prior to December 15, 2017, by the Company of the offering contemplated by the registration statement on Form S-1 that was filed with the SEC on October 11, 2017 the following shall occur: (i) pursuant to Section 3(b) of the Restricted Notes, the Company shall be deemed (as adjusted downward by the Black-Scholes value of the warrants being issued in this offering) to have automatically, and irrevocably, adjusted the conversion price of the Notes to 200% of the purchase price of a share of our common stock in the offering contemplated by the registration statement, (ii) the maturity date (as defined in the notes) shall automatically be extended to the earlier to occur of (x) the first anniversary of the date of consummation of the offering contemplated by the registration statement and (y) December 30, 2018, (iii) until the earlier of (x) this maturity date and (y) the 75th calendar day after the date of consummation of the offering contemplated by the registration statement, all installments to be made under the notes shall be deemed automatically deferred with no conversions during that 75 day period, (iv) the Company agreed to redeem any portion of the outstanding notes at any time requested by either investor thereto with $7.3 million in cash to be reduced by $0.6 million to redeem the Series C Preferred Stock remaining in the restricted accounts with respect to the 2016 convertible notes and (v) the conversion floor price on

the notes is $0.05 and not subject to adjustments.

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On September 21, 2017, we entered into a securities purchase agreement (the SPA) with two of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $0.5 million aggregate purchase price for 590 shares of Series C Preferred Stock (the Series C Preferred Shares). The purchase of the Series C Preferred Stock is being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended. The Series C Preferred Shares shall be entitled to 2,968 votes and may only vote on approval of a reverse split of our outstanding common stock. The Series C Preferred Stock has no dividend, liquidation or other preferential rights to our common stock, and each share of Series C Preferred Stock shall be redeemable for the amount of $1,000.00, payable in cash, per share at our written election, and must be redeemed by us no later than December 21, 2017. The Series C Preferred Stock was redeemed for $590,000 in November 2017.

On November 15, 2017, Delcath Systems, Inc. (the Company) entered into exchange agreements (Exchange Agreements) with each of the two investors from its June 2016 private placement of senior secured convertible notes as contemplated by that certain Securities Purchase Agreement, dated June 6, 2016, by and among the Company and such investors. As of November 15, 2017, those investors held $11,157,970 aggregate principal amount of investor notes (the Investor Notes), including (a) such aggregate principal amount of the Investor Notes as set forth on the signature page of the Investor hereto that does not include Restricted Principal as of the date hereof and all accrued and unpaid interest under the Investor Notes (such portion of the Investor Notes, the Unrestricted Investor Notes) and such aggregate principal amount of the Investor Notes as set forth on the signature page of the investors hereto that solely consists of Restricted Principal as of the date hereof (such portion of the Investor Notes, the Restricted Investor Notes).

On November 15, 2017, the Company authorized a new series of senior secured convertible notes of the Company, in the aggregate original principal amount as set forth above (the Exchange Notes), which Exchange Notes shall be convertible into shares of Common Stock in accordance with the terms of the Exchange Notes. Subject to the terms and conditions of the Exchange Agreements, the Company and the investors exchanged (the Exchange) the Unrestricted Investor Notes for (a) $10,562,425 aggregate principal amount of the Exchange Notes (the New Notes , and the shares of Common Stock issuable pursuant to the terms of the New Notes, including, without limitation, upon conversion or otherwise, collectively, the New Conversion Shares) and (b) warrants to purchase an aggregate of 14,000 shares of Common Stock (the New Warrants , as exercised, the New Warrant Shares).

The New Conversion Shares and the New Warrant Shares are collectively referred to herein as the New Underlying Securities and, together with the New Notes and the New Warrants, the New Securities .

The New Notes, which were satisfied in full on December 28, 2017, bore the following terms:

The New Notes did not bear interest except upon the occurrence of an event of default upon which the interest rate is 15% per annum.

The initial conversion price was $750.00 per share for an optional conversion and at any time, an investor could have instead engaged in an alternate conversion for which the conversion price is 82% (75% if an event of default) of the lowest volume weighted average price for the Company s common stock on the three trading days prior to and including the date of the conversion. All conversions attributable to the Restricted Notes could have been converted at the lower of the optional conversion price and the alternate conversion price, then in effect.

The obligation to prepay the Notes was extended to June 30, 2018, except in the case of an event of default or change in control.

Assuming equity conditions as stated in the New Notes are met, the investors would consent to release cash to the Company from the existing controlled accounts upon conversion of the New Notes.

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The New Notes contained provisions waiving Section 8 of the Restricted Investor Notes, including, without limitation, any requirements for the Company to effect installment conversions or redemptions.

The New Notes contained customary and usual terms including but not limited to, events of default upon failure to trade on an eligible market, failure to timely deliver shares upon conversion, failure to maintain converted share reserve, for conversions, failure to make payments thereunder when due, failure to remove legends, cross defaults to other indebtedness, bankruptcy and the like, and any material adverse effect in the Company s financial condition, as well as remedies and negative covenants substantially similar to those in the Investor Notes.

The New Warrants bear the following terms:

The Warrants will be exercisable for five years from the date of issuance.

The initial exercise price of the warrants is 115% of the closing bid price of the Company s common stock as of the trading day ended immediately prior to the time of execution of the Exchange Agreement.

The Warrants contain full antidilution ratchet protection from lowered price securities issuances subsequent to the date of issuance for six months from the date of issuance and most favored nations protection for a year from the date of issuance.

The Warrants are exercisable on a cashless basis to the extent at any time commencing on the one year anniversary of the date of issuance the issuance of underlying securities is not covered by an effective registration statement.

To the extent the investors elect to apply any amounts in their controlled accounts to the balances of the New Notes, the number of shares into which the applicable New Warrant is exercisable shall be reduced by a formula set forth in the New Warrants.

On December 28, 2017, we entered into exchange agreements (collectively, Exchange Agreements), each by and between us and an investor from its June 2016 private placement of senior secured convertible notes (as further exchanged, the Notes) originally issued pursuant to that certain Securities Purchase Agreement, dated June 6, 2016, by and among us and such investors. Pursuant to the Exchange Agreements, we (i) extinguished our remaining $3,027,408 in outstanding obligations under the Notes in full, (ii) obtained a release of restrictions on $2,046,897.66 in restricted cash held in our control accounts, (iii) issued to the investors shares (the Shares) of our common stock (or rights (Rights) to receive common stock to the extent such issuance of Shares would otherwise result in the beneficial ownership by any such investor of more than 4.9% or 9.9% of our issued and outstanding stock), as applicable, of an aggregate of 247,417 shares of our common stock (in each case, subject to trading restrictions set forth in leak out agreements we separately entered into with each investor (collectively, the Leak-Out Agreements)) and (iv) a cash payment to the investors of $829,830.54 from the restricted cash held in our control accounts. The number of shares of our issued and outstanding common stock immediately following issuance of the initial Shares to the investors is 228,110.

The Rights may be exercised in whole or in part by an investor, without payment of additional consideration, at any time an investor would not beneficially own more than 4.9% or 9.9% (as set forth in the applicable Exchange Agreement) of our common stock (along with any shares of our common stock owned by any Attribution Parties) outstanding immediately after giving effect to such exercise. The Shares and Rights were issued in transactions exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and the Shares and Rights were also issued in compliance with Section 3(a)(9) thereunder such that for Rule 144 purposes the holding period for the Shares and Rights and shares of our common stock underlying the Rights may be tacked onto the holding period of the Notes.

As of the date of this Prospectus, all of the Rights have been exercised, and neither investor owns more than 4.9% of the issued and outstanding shares of our common stock.

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June 2018 Private Placement

On June 4, 2018, pursuant to a Securities Purchase Agreement (Securities Purchase Agreement) between the Company and the selling stockholder (Investor), the Company sold 8% Senior Secured Convertible Promissory Notes (Notes) and pre-paid Series C Warrants and received gross proceeds of $2,400,000. The Investor is a non-U.S. person and the transaction was exempt from registration under Regulation S as amended promulgated under the Securities Act of 1933.

The Securities Purchase Agreement contains customary representations and warranties of the Purchasers and the Company regarding the purchase and sale, respectively, of the Notes and Series C Warrants. Under the Securities Purchase Agreement, the Company makes certain covenants including, but not limited to: (i) timely filing of its reports with the Securities and Exchange Commission (the SEC) under the Securities Exchange Act of 1934, as amended (the Exchange Act), (ii) provision of certain financial information to the Purchasers, (iii) maintaining the listing of the shares of Common Stock on an eligible market, and (iv) payment of certain fees of the Purchasers. The Securities Purchase Agreement also contains certain market provisions including piggyback registration rights, prohibition on shorting the Company s stock by the Purchaser and the like.

The terms of the two Notes are as follows:

	Note A	Note B
Face Amount	$2,511,574	$837,191
Purchase Price	$1,702,847	$567,616
Term	6 months	18 Months
Interest Rate	8%, accrued and unpaid interest payable quarterly in cash during the term of the Note through maturity.	8%; The Company shall pay interest to the Holder on the aggregate principal amount of this Note at the rate of eight percent (8%) per annum on a monthly basis beginning seven (7) months after the Closing Date. Following the Closing Date, all interest payments hereunder shall be payable in cash. Accrued and unpaid interest shall be due and payable on each Conversion Date, each Amortization Payment Date, on the Maturity Date, or as otherwise set forth herein on any remaining principal balance of the Note.
Per Share conversion Price	$3.00	$3.00
Original Issue Discount	32%	32%
Repayment	On the maturity date thereof but if not paid on the maturity date, there is	Commencing seven (7) months following the Closing Date and

a 90 day grace period although an extra 20% OID payment is added so that the principal amount increases by 20%.

continuing monthly thereafter for a total period of twelve (12) months (each, an Amortization Payment Date), the Company shall redeem one-twelfth (1/12th) of the

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	Note A	Note B
		outstanding principal amount of this Note (Principal Amortization Amount), accrued but unpaid interest and the Make-Whole Amount (each, an Amortization Payment). Each Amortization Payment shall be paid in cash or, provided that the Market Price is at least the Conversion Price, at the option of the Company, upon ten (10) Trading Days written notice to the Holder, in free trading Common Stock at the Conversion Price. Any outstanding unpaid principal and accrued but unpaid interest on this Note as of the Maturity Date will be due and payable on the Maturity Date in cash or, provided that the Market Price is at least the Conversion Price, at the option of the Company, upon ten (10) Trading Days written notice to the Holder, in free trading Common Stock at the Conversion Price.
Prepayment	At any time upon 10 day notice to the Purchaser without premium and mandatory upon the closing of a public financing of at least $10,000,000	
Prohibition on Certain Transactions	No variable rate transactions or dilutive issuances so long as Notes and Warrants outstanding	No variable rate transactions or dilutive issuances so long as Notes and Warrants outstanding
Maturity Default	Upon the occurrence of a Maturity Default, at the option of the Company, the Company may pay the outstanding principal amount of the Note, accrued but unpaid interest and other amounts owing to the Holder in shares of Common Stock at the Conversion Price. In addition, upon the occurrence of a Maturity Default, the Company shall pay the Holder an additional twenty percent (20%) original issue discount on the purchase price of the Note by	None.

increasing the original principal
amount of the Note, which shall

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	Note A	Note B
	be payable, at the option of the Company, in cash or shares of Common Stock at the Conversion Price (the OID Payment). For the avoidance of doubt, upon the occurrence of a Maturity Default, the Company shall increase the original principal amount of the Note to $3,606,480. Upon the occurrence of a Maturity Default, the Holder may continue to convert the Note at the Conversion Price until any amounts owing to the Holder under the Note are fully paid. For the avoidance of doubt, failure by the Company to pay the Holder the (i) outstanding principal amount of the Note, accrued but unpaid interest and other amounts owing to the Holder in cash or shares of Common Stock at the Conversion Price and (ii) the OID Payment within ninety (90) days of the occurrence of a Maturity Default shall constitute an Event of Default under Section 6(a) hereof.	

Under the Notes, the holders will have certain rights upon an Event of Default. Such rights include (i) the right to require the Company to redeem all or any portion of the Notes by delivery of written notice thereof to the Company, subject to certain requirements set forth in the SPA and (ii) receipt of payment in cash of an amount equal to (a) the remaining principal amount of the Notes, accrued and unpaid interest and accrued and unpaid Late Charges (as defined in the Notes) on such principal and interest, multiplied by (b) the redemption premium, equal to 125%, in addition to any and all other amounts due thereunder.

In conjunction with the purchase of the Notes, the Company issued the Investor two types of warrants to purchase its common stock (the first being called the D-1 Warrant and the second being a series of 12 called the D-2 Warrants). All of the D-2 Warrants are subject to being repurchased by the Company at its option provided it is not in default.

The Notes will also provide the holders with certain rights, and the Company with certain obligations, upon the occurrence of a fundamental transaction, including but not limited to the obligation of the Company or successor entity to offer to redeem the Notes for an 25% premium in connection with a change of control and the obligation of a successor entity to assume the Company s obligations thereunder.

The Company will make certain negative covenants in the Notes, pursuant to which the Company agrees not to, and will cause each of its subsidiaries not to: (a) incur or guarantee, assume or suffer to exist any indebtedness, other than permitted indebtedness; (b) allow or suffer to exist any mortgage, lien, pledge, charge, security interest or other encumbrance upon or in any property or assets of the Company or any of its subsidiaries other than permitted liens; (c) redeem, defease, repurchase, repay or make any payments in respect of, by the payment of cash or cash equivalents all or any portion of any indebtedness other than the Notes if at the time such payment is due or is otherwise made or, after giving effect to such payment, an Event of Default has occurred and is continuing; (d) redeem, repurchase or

declare or pay any cash dividend or distribution on any of its capital stock;

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(e) permit any indebtedness of the Company or its subsidiaries to mature or accelerate prior to the ninety-one (91) calendar day anniversary of the maturity date; (f) make any changes in the nature of its business nor modify the Company s or any of its subsidiaries corporate structure or purpose; or (g) issue any Notes or any other securities that would cause a breach or default under the Notes or the Series C Warrants.

The Company will make certain affirmative covenants in the Notes, pursuant to which the Company agrees to, and will cause each of its subsidiaries to: (a) maintain and preserve its existence, rights and privileges, and become or remain, and cause each of its subsidiaries to become or remain, duly qualified and in good standing in each jurisdiction in which the character of the properties owned or leased by it or in which the transaction of its business makes such qualification necessary; (b) maintain and preserve all of its properties which are necessary or useful in the proper conduct of its business in good working order and condition, ordinary wear and tear excepted, and comply, and cause each of its subsidiaries to comply, at all times with the provisions of all leases to which it is a party as lessee or under which it occupies property, so as to prevent any loss or forfeiture thereof or thereunder; (c) maintain all of its intellectual property rights that are necessary or material to the conduct of its business; and (d) maintain insurance with responsible and reputable insurance companies or associations with respect to its properties and business, in such amounts and covering such risks as is required by any governmental authority having jurisdiction with respect thereto or as is carried generally in accordance with sound business practice by companies in similar businesses similarly situated.

The Warrants

Events of Default under the Notes includes (subject, in certain cases to cure periods, as set forth therein): (i) default in any payment due under the Note when due, except with respect to interest due, for which there is a three trading day grace period; (ii) failure to perform other covenants under the Notes by the Company; (iii) cross default to defaults under any other transaction document or material agreement not cured within the applicable cure period provided or misrepresentation under any such agreement; (iv) bankruptcy event of the Company or a significant subsidiary, as defined; (v) default under any credit agreement or the like in excess of $100,000 or if the breach causes an acceleration of the instrument; (vi) the Company becomes ineligible for listing on its trading market which continues for at least five trading days or the Company s shares are ineligible for DTC transfer; (vii) there is a change of control transaction as defined; (viii) the Company is not current in its Exchange Act reporting requirements; (ix) Company does not meet share delivery requirements under the transaction documents; (x) failure to meet Rule 144 current reporting requirements; (xi) the Company files for bankruptcy, appoints a receiver or similar, whether voluntary or involuntary (and if involuntary remains for more than 60 days); (xii) an attachment of Company property worth more than $100,000; (xiii) failure to maintain share reserves; (xiv) a maturity default of the Note, not cured within the 90 day cure period or (xv) the occurrence of any event described in Rule 506(d)(1) under the Securities Act, (2) the Company or any subsidiary is indicted, charged with or convicted of any crime, (3) any Affiliate of the Company or any person who is an officer, director or member of senior management of the Corporation or any subsidiary is arrested, indicted, charged with or convicted of any felony other crime involving moral turpitude, or (4) a government enforcement or regulatory agency files a complaint in any court or institutes administrative proceedings in any jurisdiction against the Corporation, any Affiliate, or any member of management.

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The terms of the two Warrants are as follows:

	Warrant D-1	Warrant D-2-101 through 113
Number	1,116,256	12,953,694 in total: 101 is 10,017,999 102 is 319,798 103 is 243,065 104 is 242,013 105 is 240,962 106 is 239,911 107 is 238,860 108 is 237,809 109 is 236,758 110 is 235,707 111 is 234,655 112 is 233,604 113 is 232,553
Term	5 years from issuance date	5 years from date of initial exercisability
Initial Exercisability Date	Issuance Date	On the fifth day of each month commencing December 5, 2018, through December 5, 2019, for each of Warrant D-2-101 through 113 respectively, will be initially exercisable
Exercise Price	$4.00	$.01
Pre Funded	No	Yes, at $.01 per share
Buy back	No	The Company may buy back each Warrant on its date of initial exercisability so long as Note A is

		not in default for Warrant D-2-101 and the applicable installment payment for each month commencing on January 4, 2019 through December 4, 2019 has been paid when due for the warrants in sequential order Warrant D-2-102 for January 4, 2019 and so forth.
Prohibition on Certain Transactions	No variable rate transactions or dilutive issuances so long as Notes and Warrants outstanding	No variable rate transactions or dilutive issuances so long as Notes and Warrants outstanding

Provide Executed Security Agreements and Subsidiary Guaranty

The Company s obligations to the Purchaser are secured by a lien on all of its assets pursuant to a security agreement and an intellectual property security agreement dated June 4, 2018, along with a subsidiary guaranty pursuant to which the Company s subsidiaries have guaranteed payment of the Company s obligations under the Notes. The security agreements create a first priority security interest in all of the personal property of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future (the Collateral), as security for the Secured Obligations (as defined in the security agreements). Under the security agreements, the Company agrees to certain conditions on its maintenance and use of the Collateral, including but not limited to the location of equipment and inventory, the condition of equipment, the payment of taxes, the maintenance of insurance, the protection of intellectual property rights, and limitations on transfers and sales. Upon the occurrence and during the continuance of an Event of Default under the Notes, the secured party will have certain rights under the security agreements including taking control of the Collateral pursuant to applicable law governing the rights and remedies of secured creditors and, in certain circumstances, selling the Collateral to cover secured obligations owed to the holders of the Notes.

The above is a summary of the material terms and conditions of the Securities Purchase Agreement, the Notes, the Warrants and the other agreements issued into in conjunction therewith and is qualified in its entirety by the full terms and conditions of such agreements which are attached to the Company s Current Report on Form 8-K, dated June 8, 2018 as Exhibit 10.1 and are hereby incorporated by reference.

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On June 4, 2018, we entered into a Backstop Commitment Purchase Agreement with an institutional investor and on July 20, 2018 we entered into the same form of agreement with Discover Growth Fund, LLC (the Backstop Agreement). Pursuant to the Backstop Agreement, the selling stockholder has agreed, subject to customary conditions out of its control, to purchase from us, on a fully committed basis, shares of common stock that would have been delivered to our stockholders upon exercise of rights that are not duly exercised prior to the expiration date of the rights offering. Such shares will be purchased for an aggregate amount equal to the aggregate subscription price and otherwise on the same terms as the shares offered to stockholders in the rights offering.

After the expiration date of the rights offering, within two business days following the satisfaction of the closing conditions contained in the Backstop Agreement, and each successive 15 business day period thereafter during the term of the Backstop Agreement, the selling stockholder and Discover Growth Fund, LLC have agreed to purchase from us up to such number of shares equal to the lesser of (i) $1,000,000 worth of shares or (ii) 20% of the dollar trading volume of our common stock on the five trading days immediately preceding the purchase date. The purchase amount may be increased on a case-by-case basis as reasonably requested by us. With respect to each such purchase, we must deliver the shares on the business day following the purchase date. The Backstop Agreement will terminate on or before June 30, 2019.

On July 20, 2018, the Company entered into a second securities purchase agreement with Discover Fund, LLC for the remaining $1.6 million in notes and warrants offered under the original SPA, except that this purchase and sale was made in a transaction exempt from registration under Rule 144 promulgated under the Securities Act of 1933. On July 20, 2018, the Company and theselling stockholder amended the Series D warrants so that they are currently exercisable.

THE SELLING STOCKHOLDER AND PLAN OF DISTRIBUTION

The shares of common stock being offered by the selling stockholder constitute a portion of those to be issued upon exercise of the warrants issued to it in the June 4, 2018 transaction.

The table below lists the selling stockholder and other information regarding the beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder) of the shares of common stock held by each of the selling stockholder. The second and third columns list the number of shares and percentage of common stock beneficially owned by the selling stockholder, based on its ownership of shares of common stock, as of August 10, 2018.

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The fourth and fifth column list the number and percentage of shares of common stock being offered by this prospectus by the selling stockholder.

Information about the selling stockholder may change over time. Any changed information will be set forth in an amendment to the registration statement or supplement to this prospectus, to the extent required by law.

Selling Stockholder	Shares of Common Stock Beneficially Owned Prior to this Offering		Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Shares of Common Stock To Be Beneficially Owned Upon Completion of this Offering (1)	
	Number	Percentage		Number	Percentage
Discover Growth Fund (2)	15,186,207(2)	4.99%(2)	3,298,516(2)	0	

(1) Assumes the selling stockholder sells all of the shares of common stock included in this prospectus.

(2) Ownership of our common stock by Discover Growth Fund includes (i) 1,116,256 shares of our common stock issuable upon the conversion of the secured notes held by the selling stockholder and (ii) 14,069,951 shares of common stock issuable upon the exercise of the Warrants held by the selling stockholder. Under the terms of the notes, the holder does not have the right to convert the notes to the extent that after giving effect to such conversion, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of the holder s affiliates) would beneficially own in excess of 4.99% (the Maximum Percentage) of the shares of our common stock outstanding immediately after giving effect to such conversion. By written notice to us, however, the holder may waive the Maximum Percentage provision, which such notice will be effective sixty-one (61) calendar days after the date of such notice. Similarly, under the terms of the Warrants, the holder does not have the right to exercise the Warrants to the extent that after giving effect to such exercise, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of the holder s affiliates) would beneficially own in excess of the Maximum Percentage. However, by sixty-one (61) days prior notice to us the holder may from time to time increase or decrease the Maximum Percentage to any other percentage not in excess of 9.99%. The numbers in the second column reflect these limitations. The selling stockholder may sell all, some or none of their shares in this offering. See Plan of Distribution. David Sims, the Director of Discover Growth Fund, is the natural person with voting and dispositive power over the shares held by the selling stockholder. The selling stockholder s address is 103 South Church Street, 4 Floor, Grand Cayman KY1-1002, Cayman Islands. Mr. Sims is not affiliated with any FINRA members. This selling stockholder acquired the securities in the ordinary course of business, and at the time of the purchase of the securities to be resold, the seller had no agreements or understandings, directly or indirectly, with any person to distribute the securities.

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PLAN OF DISTRIBUTION

We are registering the shares of common stock described above under Selling Stockholder by the holder thereof. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholder may sell all or a portion of the shares of common stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholder will be responsible for underwriting discounts or commissions or agent s commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

in the over-the-counter market;

in transactions otherwise than on these exchanges or systems or in the over-the-counter market;

through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales made after the date the Registration Statement is declared effective by the SEC;

broker-dealers may agree with a selling security holder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

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The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act of 1933, as amended, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus. If the selling stockholder effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholder or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholder may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholder may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholder may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling stockholder may pledge or grant a security interest in some or all of the notes, warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholder to include the pledgee, transferee or other successors in interest as selling stockholder under this prospectus. The selling stockholder also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the selling stockholder and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be underwriters within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholder and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing

may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be $25,000 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or blue sky laws; provided, however, a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholder against liabilities, including some liabilities under the Securities Act in accordance with the registration rights agreements or the selling stockholder will be entitled to contribution. We may be indemnified by the selling stockholder against civil liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreements or we may be entitled to contribution.

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Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

Certain legal matters will be passed upon for us by Wexler, Burkhart, Hirschberg & Unger, LLP, Garden City, New York, including the validity of the common stock offered hereby.

EXPERTS

The audited consolidated financial statements included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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.

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Consolidated Financial Statements

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Grant Thornton LLP

757 Third Avenue, 9th Floor

New York, NY

T 212.599.0100

F 212.370.4520

www.GrantThornton.com

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Delcath Systems, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc. (a Delaware corporation) and subsidiaries (collectively, the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, changes in stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and as of December 31, 2017 has an accumulated deficit of $324.8 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are also discussed in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the Company s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material

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

/s/ GRANT THORNTON LLP

We have served as the Company s auditor since 2015.

New York, New York

March 16, 2018 (except for the matter described in Note 15, fifth paragraph, as to which the date is May 2, 2018)

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DELCATH SYSTEMS, INC.

Consolidated Balance Sheets as of December 31, 2017 and 2016

(in thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 3,999	$ 4,409
Restricted cash	1,325	27,287
Accounts receivables, net	317	403
Inventories	1,248	660
Prepaid expenses and other current assets	700	698
Deferred financing costs		699
Total current assets	7,589	34,156
Property, plant and equipment, net	1,298	1,083
Total assets	$ 8,887	$ 35,239
Liabilities and Stockholders Equity (Deficit)		
Current liabilities		
Accounts payable	$ 3,846	$ 594
Accrued expenses	3,408	3,407
Convertible notes payable, net of debt discount		13,343
Warrant liability	560	18,751
Total current liabilities	7,814	36,095
Deferred revenue		30
Other non-current liabilities	395	604
Total liabilities	8,209	36,729
Commitments and contingencies		
Stockholders Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively		
Common stock, $.01 par value; 500,000,000 shares authorized; 228,140 and 24 shares issued and 228,139 and 23 shares outstanding at December 31, 2017 and December 31, 2016, respectively*	2	
Additional paid-in capital	325,517	277,790
Accumulated deficit	(324,832)	(279,188)
	(51)	(51)

Treasury stock, at cost; 1 share at December 31, 2017 and December 31, 2016, respectively*		
Accumulated other comprehensive loss	42	(41)
Total stockholders equity (deficit)	678	(1,490)
Total liabilities and stockholders equity (deficit)	$ 8,887	$ 35,239

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016, a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Consolidated Statements of Operations and Comprehensive Loss

for the Years Ended December 31, 2017, 2016 and 2015

(in thousands, except share and per share data)

	Year ended December 31,		
	2017	**2016**	**2015**
Revenue	$ 2,715	$ 1,992	$ 1,747
Cost of goods sold	(701)	(550)	(462)
Gross profit	2,014	1,442	1,285
Operating expenses:			
Selling, general and administrative expenses	9,684	9,434	10,009
Research and development expenses	10,495	8,448	6,486
Total operating expenses	20,179	17,882	16,495
Operating loss	(18,165)	(16,440)	(15,210)
Change in fair value of the warrant liability, net	15,103	12,780	564
Gain on warrant extinguishment	9,613		
Loss on debt settlements and extinguishments	(29,924)		
Interest expense	(21,703)	(14,328)	(67)
Other income (expense)	(41)	17	9
Net loss	$ (45,117)	$ (17,971)	$ (14,704)
Other comprehensive loss:			
Foreign currency translation adjustments	$ 83	$ (33)	$ (28)
Comprehensive loss	$ (45,034)	$ (18,004)	$ (14,732)
Common share data:			
Basic and diluted loss per share*	$ (3,250)	$ 1,853,500)	$ (2,548,000)
Weighted average number of basic and diluted shares outstanding*	14,039	10	6

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016, a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

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DELCATH SYSTEMS, INC.

Consolidated Statements of Stockholders Equity (Deficit)

for the Years Ended December 31, 2017, 2016 and 2015

(in thousands, except share data)

	Common Stock Issued $0.01 Par Value*		In Treasury*		Additional		Accumulated Other	Total
	# of Shares	Amount	# of shares	Amount	Paid-in Capital*	Accumulated Deficit	Comprehensive (loss) income	Stockholders Equity (Deficit)
Balance at December 31, 2014	5		(1)	$ (51)	$ 264,689	$ (246,513)	$ 20	$ 18,145
Compensation expense for issuance of stock options					349			349
Compensation expense for issuance of restricted stock					308			308
Sale of common stock, net of expenses	4				8,479			8,479
Exercise of warrants					176			176
Fair value of warrants issued classified as liability					(4,247)			(4,247)
Fair value of warrants exercised					123			123
Net loss						(14,704)		(14,704)
Foreign currency translation							(28)	(28)
Balance at December 31, 2015	9	$	(1)	$ (51)	$ 269,877	$ (261,217)	$ (8)	$ 8,601
Compensation expense for issuance of stock options					161			161
Compensation expense for issuance of restricted stock					266			266
Sale of common stock, net of expenses	2				1,011			1,011
Issuance of common stock for payments made in shares on convertible notes payable	10				649			649
Fair value of beneficial conversion feature of convertible note					4,435			4,435
Fair value of warrants issued classified as liability					(707)			(707)
Exercise of warrants	3				1,372			1,372

Fair value of warrants exercised				726			726
Net loss					(17,971)		(17,971)
Foreign currency translation						(33)	(33)
Balance at December 31, 2016	24	$ (1)	$ (51)	$ 277,790	$ (279,188)	$ (41)	$ (1,490)
Compensation expense for issuance of stock options				50			50
Compensation expense for issuance of restricted stock		0		79			79
Issuance of common stock and rights for payments made in shares on convertible notes payable	227,287	2		40,119			40,121
Fair value of beneficial conversion feature of convertible note				4,908			4,908
Series B preferred stock dividend					(527)		(527)
Warrants exercised	736			19			19
Fair value of warrants exercised				2,552			2,552
Adjustment for rounding related to Nov 2017 reverse stock split	93						
Net loss					(45,117)		(45,117)
Foreign currency translation						83	83
Balance at December 31, 2017	228,140	$ 2	(1) $ (51)	$ 325,517	$ (324,832)	$ 42	$ 678

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016, a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Consolidated Statements of Cash Flows

for the Years Ended December 31, 2017, 2016 and 2015

(in thousands)

	Year ended December 31,		
	2017	**2016**	**2015**
Cash flows from operating activities:			
Net loss	$ (45,117)	(17,971)	(14,704)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	50	161	349
Restricted stock compensation expense	79	266	308
Depreciation expense	310	305	617
Loss on disposal of equipment	18	1	15
Warrant liability fair value adjustment	(15,103)	(12,780)	(564)
Gain on warrant extinguishment	(9,613)		
Non-cash interest income	(1)	(1)	(1)
Debt discount and deferred finance costs amortization	21,544	14,268	
Loss on debt settlements and extinguishments	29,924		
Changes in assets and liabilities:			
Decrease in prepaid expenses and other assets	7	260	9
(Increase) decrease in accounts receivable	108	(138)	(52)
Decrease (increase) in inventories	(543)	95	(420)
Increase (decrease) in accounts payable and accrued expenses	3,180	1,507	(1,757)
Increase (decrease) in deferred revenue	(32)	30	
Decrease in other non-current liabilities	(209)	(216)	(220)
Net cash used in operating activities	(15,398)	(14,213)	(16,420)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(524)	(258)	(170)
Increase in restricted cash		(1,087)	
Proceeds from sales of property, plant and equipment			180
Net cash (used in) provided by investing activities	(524)	(1,345)	10
Cash flows from financing activities:			
Increase in restricted cash		(26,200)	
Net proceeds from the release of restricted cash	13,120		
Release of restricted cash for extinguishment of Series C Warrants	7,876		
Cash paid to extinguish of Series C Warrants	(7,876)		
Net proceeds from sale of Series B and Series C preferred shares	2,310		
	2,360		

Release of restricted cash for redemption of Series A and Series B preferred shares			
Cash paid to redeem Series A and Series B preferred shares	(2,360)		
Release of restricted cash for redemption of Series C Preferred Shares	590		
Cash paid to redeem Series C preferred shares	(590)		
Net proceeds from convertible note debt financing		31,226	
Net proceeds from sale of stock and exercise of warrants	15	2,383	8,655
Net cash provided by financing activities	15,445	7,409	8,655
Fx effect on cash	67	(49)	(107)
Increase (decrease) in cash and cash equivalents	(410)	(8,198)	(7,862)
Cash and cash equivalents at beginning of period	4,409	12,607	20,469
Cash and cash equivalents at end of period	$ 3,999	$ 4,409	$ 12,607
Supplemental non-cash activities:			
Conversion of convertible notes	$ 40,121	$ 649	$
Fair value of warrants issued	$ 16,953	$ 28,472	$ 4,247
Cashless exercise of warrants	$ 2,537	$	$
Deemed dividend	$ 527	$	$
Fair value of warrants exercised for cash	$ 19	$ 726	$ 123

See Accompanying Notes to these Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2017, 2016 and 2015

(1) Description of Business

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

Our 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.

Liquidity

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and has accumulated deficit of $324.8 million at December 31, 2017. As shown in the accompanying financial statements during the year ended December 31, 2017, the Company incurred net losses of $45.1 million and used $15.4 million of cash for its operating activities. These factors among others raise substantial doubt about the Company s ability to continue as a going concern for a reasonable period of time.

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

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations through May 2018. Additional working capital will be required to continue operations. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development and clinical trial results; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Consolidated Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles in the United States of America (GAAP). The preparation of consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company s consolidated financial statements. The consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated.

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2017, 2016 and 2015

(3) Summary of Significant Accounting Policies

Use of Estimates

The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company s consolidated balance sheets and the amount of revenues and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, impairment of long-lived assets, income taxes and operating expense accruals. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Cash Equivalents and Concentrations of Credit Risk

The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded as restricted cash on the accompanying consolidated balance sheets.

Accounts Receivable

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

Inventories

Inventories are valued at the lower of cost or market value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory.

Prior to obtaining authorization to affix the CE Mark to its Generation Two CHEMOSAT System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of December 31, 2017 includes finished goods and components that have been purchased since April 2012. Therefore, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company s cost of goods sold will be impacted accordingly.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2017, 2016 and 2015

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

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with Accounting Standards Codification (ASC) 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2017 and 2016, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company adheres to ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity s own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly

quoted intervals.

Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity s own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

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Revenue Recognition

Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Deferred Revenue

Deferred revenue on the accompanying consolidated balance sheets includes payment received for product sales to a distributor. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied.

Selling, General and Administrative

Selling, general and administrative costs include personnel costs and related expenses for the Company s sales, marketing, general management and administrative staff, recruitment, costs related to the Company s commercialization efforts in Europe, professional service fees, professional license fees, business development and certain general legal activities. All such costs are charged to expense when incurred.

Research and Development

Research and development costs include the costs of materials used for clinical trials and R&D, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company s proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation

is subject to periodic adjustment as the underlying equity instrument vests. The Company expenses its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair

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market value of Delcath s common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath s stock over the option s expected term, the risk-free interest rate over the option s expected term, and Delcath s expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the ASC 740 Income Taxes. Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company applies the accounting guidance issued to address the accounting for uncertain tax positions. This guidance clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements as well as provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company classifies interest and penalty expense related to uncertain tax positions as a component of income tax expense. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. See Note 13 for additional information.

Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all stock options, unvested restricted stock and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the years ended December 31, 2017, 2016 and 2015 are as follows:

(in thousands, except share data)	**2017**	**2016**	**2015**

Net loss	$ (45,117)	$ (17,971)	$ (14,704)
Preferred stock dividends	(527)		
Net loss, adjusted	(45,644)	(17,971)	(14,704)
Net loss per share basic and diluted	(3,250)	(1,853,500)	(2,548,000)
Weighted average shares outstanding basic and diluted	14,039	10	6

In the third quarter of 2017, the Company issued Series B Preferred Shares. A portion of the redemption price of the Series B Preferred Shares was accounted for as a deemed dividend and is discussed further in Note 10.

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

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For the years ended December 31, 2017, 2016 and 2015, the following potentially dilutive securities were excluded from the computation of diluted earnings per share (EPS) because their effects would be antidilutive.

Shares excluded from the computation of diluted EPS:

	2017	2016	2015
Stock options			
Unvested restricted shares			
Warrants	14,049	41	65
Total	14,049	41	63

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of CHEMOSAT/Melphalan/HDS. A single management team that reports to the CEO and President comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Foreign Currency and Currency Translation

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

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

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

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASU 2014-09) that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to

depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for the Company beginning in its fiscal year 2018, and may be applied retrospectively to all prior periods presented or through a cumulative adjustment to the opening retained earnings balance in the year of

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for the Years Ended December 31, 2017, 2016 and 2015

adoption. The Company will adopt this standard on January 1, 2018 using the modified retrospective method. The Company has completed an analysis of its existing product sales and distribution agreement and assessed the differences in accounting for each under ASU 2014-09 compared with current revenue accounting standards. Based on that review, the Company does not expect the implementation of ASU 2014-09 to have a material quantitative impact on its consolidated financial statements as the timing of revenue recognition for product sales is not expected to change considerably.

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

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

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company will adopt this standard on January 1, 2018 and does not anticipate that this guidance will materially impact its consolidated financial statements.

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

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(4) Inventories

Inventories consist of:

(in thousands)	December 31, 2017	December 31, 2016
Raw materials	$ 298	$ 346
Work-in-process	721	214
Finished goods	229	100
Total Inventory	$ 1,248	$ 660

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(in thousands)	December 31, 2017	December 31, 2016
Insurance premiums	$ 421	$ 501
Financing costs	70	
Security deposit	50	50
Other[1]	159	147
Total prepaid expenses and other current assets	$ 700	$ 698

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at December 31, 2017 and 2016.

(6) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	December 31, 2017	December 31, 2016
Buildings and land	$ 579	$ 556
Enterprise hardware and software	1,744	1,532
Leaseholds	1,705	1,504
Equipment	971	940
Furniture	175	354
Property, plant and equipment, gross	5,174	4,886
Accumulated depreciation	(3,876)	(3,803)
Property, plant and equipment, net	$ 1,298	$ 1,083

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was $0.3 million, $0.3 million, $0.6 million, respectively.

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(7) Current Accrued Expenses

Current accrued expenses include the following:

(in thousands)	December 31, 2017	December 31, 2016
Clinical trial expenses	$ 869	$ 1,365
Compensation, excluding taxes	1,124	933
Professional fees	221	286
Short-term portion of lease restructuring	209	216
Other[1]	985	607
Total accrued expenses	$ 3,408	$ 3,407

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2017 and 2016.

(8) Restructuring Expenses

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, the Company entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement (Sub-lease #1) for approximately one-half of the office space at this location (Suite 3500), resulting in a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement (Sub-lease #2) for the remaining one-half of office space at its 810 Seventh Avenue office (Suite 3505), resulting in a lease restructuring reserve of approximately $0.7 million. As of December 31, 2017, the total remaining lease restructuring liability for its leased office space was approximately $0.6 million, of which approximately $0.2 million and $0.4 million were included in Accrued expenses and Other non-current liabilities on the consolidated balance sheets, respectively.

The following table provides the year-to-date activity of the Company s restructuring reserves as of December 31, 2017:

(in thousands)	Lease Liability
Reserve balance at December 31, 2016	$ 820
Charges	

Payments/Utilizations		(216)
Reserve balance at December 31, 2017	$	604

(9) Convertible Notes Payable

As of December 31, 2017, the senior secured convertible notes (the Notes) had been repaid in full and were no longer outstanding.

On June 6, 2016, the Company entered into a Securities Purchase Agreement (the SPA) with certain investors named on the Schedule of Buyers attached to the SPA pursuant to which the Company issued $35.0 million in principal face amount of Notes and related Series C Warrants (the Series C Warrants) to purchase additional shares of the Company s common stock, par value $0.01 per share (Common Stock). $35.0 million of the Notes were issued for cash proceeds of $32.2 million with an original issue discount in the amount of $2.8 million. The Notes were secured pursuant to a Security Agreement which creates a first

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priority security interest in all of the personal property (other than Excluded Collateral (as defined in the Security Agreement) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future.

Under the terms of the Notes, at closing the Company received an initial tranche of $3.0 million for immediate use for general corporate purposes. A second tranche of $3.0 million was released to the Company in December 2016. The balance was released throughout 2017.

In connection with the issuance of the Notes under the SPA, the Company also issued Series C Warrants, exercisable to acquire approximately 40 shares of Common Stock. The provisions in the Series C Warrants required the Company to account for the warrants as derivative liabilities. The Company recognized a discount to debt of $27.8 million related to the initial fair value of the Series C Warrants. On April 2, 2017 the Company entered into separate warrant repurchase agreements (the Warrant Repurchase Agreements) with each of the investors named on the Schedule of Buyers attached to the SPA. Pursuant to the Warrant Repurchase Agreements, each investor agreed to a Controlled Account Release, in an aggregate amount equal to $7.9 million, which funds in each case were paid to the respective investor, in exchange for cancellation of the Warrants issued to each investor under the SPA. As a result of the extinguishment, the Company recognized a gain of $9.6 million, representing the difference between the fair value of the liability as of the extinguishment date of $17.5 million related to the Series C Warrants and the $7.9 million in cash returned to the Note holders to extinguish the liability.

The Company had agreed to make amortization payments with respect to the Notes in fourteen (14) equal installments beginning seven (7) months after the original date of issuance of June 13, 2016 (each, an Installment Date). On each installment date, assuming certain equity conditions were met, the installment payment was, at the election of the Company, automatically converted into shares of Common Stock at a conversion rate defined in the SPA. If the Company could not meet the equity conditions, it would have been required to repay some or all of the amounts due under the notes in cash. At any time after the issuance of the Notes, the Notes were convertible at the election of the holder into shares of our Common Stock at a conversion price equal to $8,537,775, subject to adjustment as provided in the Notes.

As a result of the Notes including a feature such that the conversion price is based upon a formula which includes discounts to the market price of the common stock as well as having a lower effective conversion price considering the issuance discount and the value allocated to the Series C Warrants, the Company has recognized a beneficial conversion feature of $4.4 million. The original issue discount, the beneficial conversion feature, and the fair value of the issuance of the Series C Warrants are collectively considered the debt discount. The Company recorded a debt discount in the amount of $35.0 million which was being amortized over the life of the Notes using the effective interest method. As of December 31, 2017, $35.0 million of the debt discount has been amortized to interest expense. All debt issuance costs were accounted for as a deferred asset and were amortized over the life of the Notes. As of December 31, 2017, the Company had incurred approximately $2.2 million in debt issuance costs all of which were amortized or expensed as of December 31, 2017.

Restructuring Agreement

On August 28, 2017, the Company entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the SPA. As of the date the Agreement was entered into, the Investor held $11,444,637 aggregate principal amount of Notes of which there was $10,092,857 aggregate Restricted Principal, (as defined in the Notes) of Notes (the Restricted Notes), secured by such aggregate cash amount held in a collateral account of the Company in the same amount (the Restricted Cash) and (y) $1,351,780 principal of Notes (the Unrestricted Notes), (ii) 4,200 shares of Series A Preferred Stock and (iii) 2,006 shares of Series B Convertible Preferred Stock.

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Pursuant to the Agreement, (a) on the date thereof the Company and the Investor took the following actions (the Initial Restructuring): (i) the Investor released restrictions on $1,650,000 of Restricted Cash (the Initial Release), (ii) the Investor consented to the use of additional Restricted Cash to effect redemptions of the Series A Preferred Shares and the Series B Preferred Shares, (iii) the Investor cancelled $1,200,000 aggregate principal of the Notes (such portion of the Notes, the Cancellation Note), (iv) the Company redeemed all the Series A Preferred Shares outstanding for a cash payment to the Investor of $4.20 and (v) the Company redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 and (b) upon the consummation of a reverse stock split of our Common Stock of at least twenty to one (the Reverse Stock Split Event , and such date, the Reverse Stock Split Date) by September 15, 2017, the Company and the Investor shall have taken the following actions (the Additional Restructuring , and together with the Initial Restructuring, the Restructuring): (i) the Investor shall consent to the use of Restricted Cash to effect redemptions of $4,000,000 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Redemption Notes), (ii) the Company shall redeem the Redemption Notes for a redemption price of $6,436,852.80 (the Redemption Price) and (iii) the Company shall exchange (the Exchange), pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, $2,436,852.80 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Exchange Notes , and together with the Redemption Notes, the Restructured Notes) for new warrants to purchase 114,286 shares of its Common Stock (the New Warrants , as exercised, the New Warrant Shares). The New Warrants expire on the 42 month anniversary of the date of issuance and bear an exercise price of $61,250 per share (which shall be adjusted to the new lower purchase price per share if there is a subsequent down round financing). The Investor, in lieu of an exercise of the New Warrants pursuant to a cash payment of the aggregate exercise price of the number of New Warrants being exercised, may exercise the New Warrants, in whole or in part, by electing instead to receive upon such exercise two shares and one hundred and twenty-five thousandths of a share of the Company s Common Stock for each Warrant Share exercised pursuant to this provision. The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act) and Rule 144(d)(3)(ii) of the 1933 Act. As a result of not having effected a reverse stock split by September 15, 2017, the Additional Restructuring did not occur.

This transaction was accounted for as a debt settlement that resulted in extinguishment. As such, the $1.9 million difference between the fair value of the common shares issued and the $1.2 million debt settlement was recorded as a loss on debt settlement.

Amendment to Restructuring Agreement

As a result of the lack of requisite approval by Delcath stockholders for the Company s proposed reverse stock split, the parties and the two investors in the Notes entered into an amendment to the August restructuring agreement on October 10, 2017 as follows: (i) on the date that the Company effects a reverse split of its common stock, (x) the Company will exchange, pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, an aggregate principal amount of those notes equal to $279,015 for new warrants to purchase an aggregate of 127,551 shares of Common Stock, and the Company shall redeem all the Series C Preferred Shares then outstanding for a cash payment of $590,000 and (ii) upon the initial consummation, on or prior to December 15, 2017, by the Company of the offering

contemplated by the registration statement on Form S-1 that was filed with the SEC on October 11, 2017 the following shall occur: (i) pursuant to Section 3(b) of the Restricted Notes, the Company shall be deemed (as adjusted downward by the Black-Scholes value of the warrants being issued in this offering) to have automatically, and irrevocably, adjusted the conversion price of the Notes to 200% of the purchase price of a share of our common stock in the offering contemplated by the registration statement, (ii) the maturity date (as defined

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in the notes) shall automatically be extended to the earlier to occur of (x) the first anniversary of the date of consummation of the offering contemplated by the registration statement and (y) December 30, 2018, (iii) until the earlier of (x) this maturity date and (y) the 75th calendar day after the date of consummation of the offering contemplated by the registration statement, all installments to be made under the notes shall be deemed automatically deferred with no conversions during that 75 day period, (iv) the Company agreed to redeem any portion of the outstanding notes at any time requested by either investor thereto with $7.3 million in cash to be reduced by $0.6 million to redeem the Series C Preferred Stock remaining in the restricted accounts with respect to the 2016 convertible notes and (v) the conversion floor price on the notes is $0.05 and not subject to adjustments. As a result of not consummating an S-1 offering by December 15, 2017, the actions contemplated in (ii) of this paragraph did not occur. This transaction resulted in the extinguishment of $0.3 million in debt in exchange for the issuance of warrants. The $2.3 million difference in the fair value of the issued warrants and the $0.3 million in extinguished debt was recorded as a loss on debt extinguishment.

November 2017 Exchange Agreement

On November 15, 2017, the Company entered into exchange agreements (Exchange Agreement) with each of the two investors from its June 2016 private placement of senior secured convertible notes as contemplated by the SPA. As of November 15, 2017, those investors held $11,157,970 aggregate principal amount of Notes. On November 15, 2017, the Company authorized a new series of senior secured convertible notes of the Company, in the aggregate original principal amount as set forth above (the Exchange Notes), which Exchange Notes convertible into shares of Common Stock in accordance with the terms of the Exchange Notes. Subject to the terms and conditions of the Exchange Agreements, the Company and the investors exchanged for (a) $10,562,425 aggregate principal amount of the Exchange Notes (the New Notes , and the shares of Common Stock issuable pursuant to the terms of the New Notes, including, without limitation, upon conversion or otherwise, collectively, the New Conversion Shares) and (b) warrants to purchase an aggregate of 14,000 shares of Common Stock at an initial exercise price of $1,225. The warrants have a five year term.

The New Notes had the following terms:

The initial conversion price was $750.00 per share for an optional conversion and at any time, an investor could have instead engaged in an alternate conversion for which the conversion price was 82% (75% if an event of default) of the lowest volume weighted average price for the Company s common stock on the three trading days prior to and including the date of the conversion.

The obligation to prepay the New Notes was extended to March 31, 2018, except in the case of an event of default or change in control.

Assuming equity conditions as stated in the New Notes are met, the investors consented to release cash to the Company from the existing controlled accounts upon conversion of the New Notes.

The November Exchange Agreement was accounted for as an extinguishment. As such, the New Notes were recorded at their calculated fair value of $15.2 million, the related November 2017 Warrants were recorded as a derivative liability at their calculated fair value of $14.4 million and the difference between the fair value of the New Notes, the fair value of the warrants issued, and the carrying amount of the old notes was recorded as a $19.0 million loss on extinguishment. As with the Notes issued in June 2016, the New Notes also contained a beneficial conversation feature. The value of this feature was considered in the fair value calculations of the New Notes and was determined to be $4.9 million of the $15.2 million total fair value. The $10.3 million fair value of the New Notes was accreted up to the face value of $10.6 million over the

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term of the New Notes with the $0.3 million difference charged to interest expense. The $4.9 million beneficial conversion feature was fully credited to Additional paid-in capital as the New Notes were fully satisfied under the December 28, 2017 Exchange Agreement. The November 2017 Warrants that were issued in connection with the November Exchange Agreement assessed at the end of each reporting period with any changes in fair value being recognized as derivative income or expense.

December 28, 2017 Exchange Agreements

On December 28, 2017, the Company entered into exchange agreements (Exchange Agreements), with each of the two investors from its June 2016 private placement of senior secured convertible notes (as further exchanged, the Notes) originally issued pursuant the SPA. Pursuant to the Exchange Agreements, the Company (i) extinguished its remaining $3,027,408 in outstanding obligations under the New Notes in full, (ii) obtained a release of restrictions on $2,046,898 in restricted cash held in its control accounts, (iii) issued to the investors 29,600 shares (the Shares) of its common stock and rights (Rights) to receive 217,800 shares of common stock to the extent such issuance of Shares would otherwise result in the beneficial ownership by any such investor of more than 4.9% or 9.9% of its issued and outstanding stock), as applicable, for an aggregate of 247,417 shares of its common stock (in each case, subject to trading restrictions set forth in leak out agreements the Company separately entered into with each) and (iv) a cash payment to the investors of $829,831 from the restricted cash held in the control accounts. The 29,600 shares were issued and outstanding at December 31, 2017. The rights were fully exercised in January 2018. This transaction resulted in the settlement of $3.0 million in debt. The $3.7 million difference between the fair value of the shares and rights issued for shares and the carrying value of the Notes was recorded as a loss on debt settlement.

The Company has issued shares of Common Stock and Preferred Stock as payments of principal (including certain early repayments at the option of the holders) and effected a retirement under the Notes and New Notes as follows:

	Number of Shares of Common Stock	Number of Shares of Preferred Stock	Applicable Conversion Price	Reduction in Principal
January 12, 2017	23		$ 63,000.00	$ 1,478,318
January 26 - February 1, 2017[1]	10		$ 56,000.00	$ 544,000
February 10, 2017	87		$ 35,000.00	$ 3,045,817
February 23 - March 2, 2017[1]	5		$ 24,500.00	$ 125,999
March 13, 2017	229		$ 19,250.00	$ 4,417,829
April 10, 2017	344		$ 10,500.00	$ 3,621,286
May 9, 2017	218		$ 8,750.00	$ 1,913,915
June 7 / July 2, 2017 Exchange Agreement[2]	1,380	4,200	$ 12,250.00	$ 4,200,000
July 7, 2017	229		$ 12,250.00	$ 2,000,000

August 4, 2017	83	$ 5,250.00	$ 1,015,848
August 28, 2017 Restructuring Agreement[3]	229	$ 5,250.00	$ 1,200,000
November 6, 2017 Warrant Exchange[4]		$	$ 279,016
November 15, 2017 Exchange Agreements[5]	194,896	$ 41.72	$ 8,130,564
Retirement per December 28, 2017 Exchange Agreements[6]		$	$ 553,234
December 28, 2017 Exchange Agreements[6]	445,152	$ 10.00	$ 2,474,174
Total	642,885		$ 35,000,000

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1 During the periods referenced above, the Company and the holders of the Notes agreed to a temporary reduction in the conversion price in order to encourage voluntary conversion of Notes by the holders thereof.

2 On July 2, 2017, the Company entered into an exchange agreement with one of its investors which had purchased Notes, for $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock. The Series A Preferred Stock shares were issued to address a short-term valuation issue for 1,380 common shares delivered to the Notes holders to close an installment period. Through the Series A Preferred Shares placement, the Company was able to value the open installment shares such that the amount of debt remaining under the Notes was reduced by $4.2 million. Additionally, the Company recognized a loss on debt settlement of $1.0 million related to this transaction.

3 On August 28, 2017, the Company entered into a restructuring agreement with one of its investors which had purchased Notes. The restructuring agreement included a provision to exchange 229 shares for $1.2 million aggregate principal amount of such Notes. Additionally, the Company recognized a loss on debt settlement of $1.9 million related to this transaction.

4 On October 10, 2017, the Company entered into an amendment to the August 28, 2017 Restructuring Agreement which included a provision to exchange debt for the issuance of warrants. Additionally, the Company recognized a loss on debt extinguishment of $2.3 million.

5 On November 15, 2017, the Company entered into an exchange agreement which included a provision to exchange 1,948 shares for $0.6 million aggregate principal amount of such Notes. Additionally, the Company issued 192,948 million shares for $7.5 million aggregate principal amount of Notes under the updated conversion price formula as discussed in more detail above. Additionally, the Company recognized a loss on debt extinguishment of $21.0 million in connection with the issuance of the New Notes and warrants as part of such exchange.

6 On December 28, 2017, the Company entered into an exchange agreement to retire $0.6 million aggregate principal amount of Notes and to issue 247,417 million shares and rights for shares for the remaining $2.5 million aggregate principal amount of Notes. Additionally, the Company recognized a loss on debt extinguishment of $3.7 million.

(10) Stockholders Equity

Reverse Stock Split

On November 6, 2017, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-three hundred and fifty (1:350) split-adjusted basis. All owners of record as of the open of the OTCQB market on November 6, 2017 received one issued and outstanding share of Delcath common stock in exchange for three hundred and fifty issued and outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by theone-for-three hundred and fifty exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying Notes have been restated to give retrospective presentation for

the reverse stock split.

On July 19, 2016, shareholders of the Company approved, through a shareholder vote, an amendment to the Company s Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath s common stock at a ratio within a range of one-for-ten (1:10) to one-for-twenty (1:20). The reverse stock split became effective on July 21, 2016 at which time Delcath s common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen (1:16) split-adjusted

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

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

Preferred Stock Issuances

Series A Preferred Stock

On June 29, 2017, the Company s Board authorized the establishment of a new series of preferred stock designated as Series A Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series A Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series A Preferred Stock). On July 2, 2017, the Company entered into an exchange agreement (the Exchange) with one of its investors which had purchased the Notes of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the Series A Preferred Shares). The Exchange was made in reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Shares were entitled to the whole number of votes equal to $4.2 million divided by $644,000.00 (the closing bid price on June 13, 2016, the date of issuance of the Notes) or 7 votes. The Series A Preferred Stock had no dividend, liquidation or other preferential rights to the Company s common stock, and each share of Series A Preferred Stock was redeemed for the amount of $0.001, paid in cash pursuant to the Restructuring Agreement signed on August 28, 2017 and discussed in further detail in Note 9.

Series B Preferred Stock

On June 29, 2017, the Company s Board authorized the establishment of a new series of preferred stock designated as Series B Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series B Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series B Preferred Stock). On July 11, 2017, the Company entered into a securities purchase agreement with existing holders of Notes pursuant to which the investors purchased $2,360,000 of Series B Preferred Stock for a cash purchase price of $2,000,000 in a private placement. The Series B Preferred Stock was entitled to the whole number

of votes equal to $2.0 million divided by $32,787 (the closing bid price on July 5, 2017, the date of the original securities purchase agreement for the Series B Preferred Stock), or 61 votes. The Series B Preferred Stock had no liquidation or other preferential rights (but had the redemption rights described below) to the Company s common stock and could have been converted into shares of common stock at a price equal to $26,775 per share upon the earlier of the date of closing to the extent that the holder thereof reallocated shares of our common stock reserved for issuance under its Notes to conversion of the Series B Preferred Shares and

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otherwise upon receipt of shareholder approval of the Reverse Stock Split. The Series B Preferred Stock allowed for optional redemption by the Company at any time after issuance or the holders at any time after the tenth business day prior to the maturity date. In the instance of a Financing, the Company was required to redeem the Series B Preferred Stock. The $360,000 difference between the redemption amount and the cash purchase price of the Series B Preferred Stock, as well as all issuance costs related to the Series B Preferred Stock, have been recorded as a deemed dividend. The Series B Preferred Stock was redeemed for $2,360,000 pursuant to the Restructuring Agreement signed on August 28, 2017 with one investor and upon a redemption notice from the second investor as discussed in further detail in Note 9.

Series C Preferred Stock

On September 12, 2017, the Company s Board authorized the establishment of a new series of preferred stock designated as Series C Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock which was filed with the State of Delaware on September 20, 2017. On September 21, 2017, the Company entered into a securities purchase agreement with the two investors which had purchased Notes of $0.5 million aggregate purchase price for 590 shares of Series C Preferred Stock. The purchase of the Series C Preferred Stock is being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended. The Series C Preferred Stock shall be entitled to 2,968 votes and may only vote on approval of a reverse split of our outstanding common stock. The Series C Preferred Stock has no dividend, liquidation or other preferential rights to the Company s common stock, and each share of Series C Preferred Stock shall be redeemable for the amount of $1,000.00, payable in cash per share at our written election, and must be redeemed no later than December 21, 2017. Because the Series C Preferred Stock was mandatorily redeemable, it has been recorded as a liability with the difference between the purchases price and the fair value being recognized over the term of the instrument. Additionally, all expenses related to the issuance of the Series C Preferred Stock are recognized as a debt discount and have been amortized over the term of the instrument. Per the terms of the October 22, 2017 Amendment to the Restructuring Agreement, the Series C Preferred Stock was redeemed for $590,000 on November 6, 2017.

Stock and Warrant Issuances

In October 2013, the Company completed the sale of 1 share of its common stock and the issuance of warrants to purchase approximately 9 common shares (the 2013 Warrants) pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2017, the 2013 Warrants were exercisable at $19,712,000 per share with 9 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 1 share of its common stock and the issuance of warrants to purchase 9 common shares (the February 2015 Warrants) pursuant to an underwriting agreement. The Company

received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At

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December 31, 2017, the February 2015 Warrants were exercisable at $24,500 per share with approximately 9 warrants outstanding. The February 2015 Warrants have a five-year term.

In July 2015, the Company completed the sale of approximately 3 Units consisting of 3 shares of its common stock, Series A Warrants to purchase up to approximately 8 common shares (Series A Warrants) and Series B Warrants to purchase Units consisting of up to approximately 3 common shares (Series B Warrants) and 8 Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the Series A and Series B Warrants. During the year ended December 31, 2016, approximately 1 Series B Warrant was exercised for net proceeds of approximately $0.8 million. The remaining 3 Series B Warrants expired on January 29, 2016 and the related liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 1 Series A Warrant was issued. The exercise price of the Series A Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At December 31, 2017, the July 2015 Series A Warrants were exercisable at $24,500 with approximately 9 warrants outstanding. The Series A Warrants have a five-year term. There was approximately 1 July 2015 Series A Warrant exercised during the year ended December 31, 2017 for proceeds of approximately $15,000. There was approximately 1 July 2015 Series A Warrants exercised during the year ended December 31, 2016 for proceeds of $0.4 million.

In June 2016, the Company entered into a SPA pursuant to which the Company issued $35.0 million in principal face amount of the Notes and related Series C Warrants to purchase 40 additional shares of the Company s common stock. The Company allocated an estimated fair value of $27.8 million to the Series C Warrants. Pursuant to the Warrant Repurchase Agreements, each investor agreed to a Controlled Account Release, in an aggregate amount equal to $7.9 million, which funds in each case are to be paid to the respective investor, in exchange for cancellation of the Series C Warrants issued to each investor under the SPA. During 2017, 224,000 common shares and rights to receive 217,800 common shares were issued to satisfy the Notes.

In October 2016, the Company completed the sale of 2 shares of its common stock and the issuance of warrants to purchase 1 common share (the October 2016 Warrants) pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At December 31, 2017, the October 2016 Warrants were exercisable at $24,500 per share with 1 warrant outstanding. The October 2016 Warrants have a five-year term. There was 1 October 2016 Series C Warrants

exercised during the year ended December 31, 2016 for proceeds of $0.1 million.

Pursuant to the October 10, 2017 Amendment to the Restructuring Agreement, 225 warrants were issued to each of the two investors from the June 2016 SPA on November 6, 2017 following the effectuation of the reverse stock split discussed earlier. The warrants contain a cashless exercise provision that allows the holders to exercise each warrant for three shares of common stock. The warrants have a 4.5 year term and an exercise price of $61,250. The exercise price is subject to appropriate adjustment in the event of stock

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dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. As of December 31, 2017, 255 warrants have been exercised resulting in the issuance of 735 common shares. 10 warrants remain outstanding at December 31, 2017.

In November 2017, the Company issued 14,049 warrants pursuant to an Exchange Agreement entered into with each of the two investors from the June 2016 SPA. The Company allocated an estimated fair value of $14.4 million to the November 2017 Warrants. The exercise price is subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At December 31, 2017, the November 2017 Warrants were exercisable at $1,225 per share with 14,049 warrants outstanding. The November 2017 Warrants have a five-year term from the date of exercisability.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $71.8 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company is not currently eligible to use its Form S-3.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the Plans) under which 0 and 0 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In July 2016, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 0 shares, from 0 to 0 shares, upon a favorable vote by the Company s stockholders. The Plans are administered by the Compensation and Stock Option Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the type, terms, conditions, option price and the duration of each award. As of December 31, 2017, there were 0 shares available to grant under the 2009 Stock Incentive Plan.

A stock option grant allows the holder of the option to purchase a share of the Company s common stock in the future at a stated price. Options and Restricted Stock granted under the Plans vest as determined by the Company s Compensation and Stock Option Committee. Options granted under the Plans expire over varying terms, but not more than ten years from the date of grant.

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Stock option activity for 2017, 2016 and 2015 is as follows:

	Stock Option Activity under the Plans[1]			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2014	0	$ 0 - $0	$ 0	0
Granted	0	0	0	0
Forfeited	(0)	0-0	0	0
Outstanding at December 31, 2015	0	$ 0 - $0	$ 0	0
Granted				
Forfeited	(0)	0-0	0	0
Outstanding at December 31, 2016	0	$ 0 - $0	$ 0	0
Granted	0	$ 0	$ 0	0
Forfeited	(0)	$ 0	$ 0	0
Outstanding at December 31, 2017	0	$ 0 - $0	$ 0	0
Exercisable at December 31, 2017	0	$ 0 - $0	$ 0	0

(1) Due to the May 2, 2018 1-for-500 reverse stock split, and no fractional shares being issued, all numbers are reduced to zero.

For the years ended December 31, 2017, 2016 and 2015 the Company recognized compensation expense related to stock option grants of approximately $0.1 million, $0.2 million and $0.3 million, respectively.

The estimated fair value of each option award granted was determined on the date of grant using an option pricing model with the following assumptions for option grants made in 2017 and 2015. There were no option grants during 2016.

	Year ended December 31, 2017	Year ended December 31, 2015
Weighted average risk-free interest rates	2.15%	1.82%

Weighted average expected volatility	170.42%	97.70%
Dividend yield		
Weighted average expected option term (in years)	7.29	5.15
Weighted average grant date fair value	$ 82.34	$ 4,964.73

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company s historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life of the stock options on the grant date. The expected option term is based on actual historical results.

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A summary of the Company s non-vested options to purchase shares as of December 31, 2017 and changes during the years ended December 31, 2017 and December 31, 2016 are presented below:

	Non-Vested Options[1]	
	Number of Options	Weighted Average Exercise Price
Non-vested at December 31, 2015	0	$ 0
Granted		
Vested	(0)	0
Forfeited	(0)	0
Non-vested at December 31, 2016	0	$ 0
Granted	0	0
Vested	(0)	0
Forfeited	(0)	0
Non-vested at December 31, 2017	0	$ 0

Additional compensation expense of approximately $6,800, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 0.42 years.

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2017 is $0. The aggregate intrinsic value represents the total pretax intrinsic value, based on options with an exercise price less than the Company s closing stock price of $450.00 as of December 31, 2017, which would have been received by the option holders had those option holders exercised their options as of that date.

A summary of the Company s restricted stock activity as of December 31, 2017 and changes during the years ended December 31, 2017 and December 31, 2016 are presented below:

	Restricted Stock Activity[1]	
	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2015		$

Granted	
Vested	
Forfeited	
Non-vested at December 31, 2016	$
Granted	
Vested	
Forfeited	
Non-vested at December 31, 2017	$

For the three years ended December 31, 2017, 2016 and 2015 the Company recognized compensation expense related to restricted stock grants of approximately $0.1 million, $0.3 million and $0.3 million, respectively.

(1) Due to the May 2, 2018 1-for-500 reverse stock split, and no fractional shares being issued, all numbers are reduced to zero.

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Warrants

The Company issued warrants as part of its offerings in 2013, 2015, and 2016 as well as part of its issuance of convertible notes in 2016 and an exchange agreement in 2017. A summary of warrant activity is as follows:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at January 1, 2014	9	$ 4,900,000-$19,712,000	$ 15,170,879	2.78
Issued	35		2,240,000	
Exercised	(-)		2,296,000	
Expired	(-)		2,296,000	
Outstanding at December 31, 2015	44	$ 2,072,000-19,712,000	$ 44,858,633	2.16
Issued	30		840,000	
Exercised	(3)		481,250	
Expired	(3)		994,000	
Outstanding at December 31, 2016	78	$ 281,750-$19,712,000	$ 910,000	5.59
Issued	14,256		2,299	
Exercised	(246)		4,221	
Expired	(39)		845,250	
Outstanding at December 31, 2017	14,049	$ 1,225-19,712,000	$ 1,569	4.88

(11) Fair Value Measurements

Derivative Financial Instruments

As disclosed in Note 10 of the Company s consolidated financial statements contained in this Annual Report on Form 10-K, the Company allocated part of the proceeds of public offerings in 2013, 2015 and 2016 of the Company s common stock to warrants issued in connection with those transactions. In addition, the Company recognized a discount to debt related to the initial fair value of warrants issued in connection with the June 2016 Convertible Notes and allocated an estimated fair value of $14.4 million to warrants issued pursuant to an exchange agreement signed in

November 2017 discussed in further detail in Note 9 of the Company s consolidated financial statements contained in this Annual Report on Form 10-K. The valuations of the October 2013, February 2015, July 2015 Series A, October 2016 and November 2017 Warrants (collectively, the Warrants) were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the Warrants as a current liability due to certain provisions relating to price adjustments and potential cash payments, as well as the holders ability to exercise the warrants within twelve months of the reporting date and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period. Additionally, the Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing models against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath s stock over that

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term; annual rate of dividends; and the risk-free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company s historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The risk-free rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

For the year ended December 31, 2017, the Company recorded pre-tax derivative instrument income of $15.1 million. The resulting derivative instrument liabilities totaled $0.6 million at December 31, 2017. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2017 was determined by using option pricing models assuming the following:

	November 2017 Warrants	October 2016 Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	217.39%	130.88%	161.87%	169.95%	266.92%
Risk free interest rates	1.98%	2.06%	1.94%	1.90%	1.68%
Expected life (in years)	4.88	3.76	2.56	2.13	0.82

The table below presents the Company s assets and liabilities measured at fair value on a recurring basis as of December 31, 2017 and 2016, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2017	2016	2017	2016	2017	2016	2017	2016
Liabilities								
Derivative instrument liabilities	$	$	$	$	$ 560	$ 18,751	$ 560	$ 18,751

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Fair Value Measurements Using Significant Unobservable

Inputs (Level 3)

(in thousands)		**Warrant Liability**
Balance at January 1, 2015	$	225
Total change in the liability included in earnings		(564)
Fair value of warrants issued		4,247
Fair value of warrants exercised		(123)
Balance at December 31, 2015		3,785
Total change in the liability included in earnings		(12,780)
Fair value of warrants issued		28,472
Fair value of warrants exercised		(726)
Balance at December 31, 2016	$	18,751
Total change in the liability included in earnings		(15,103)
Extinguishment of convertible note warrant		(17,489)
Fair value of warrants issued		16,953
Fair value of warrants exercised		(2,552)
Balance at December 31, 2017	$	560

(12) Commitments

Operating Leases

In February 2010, the Company entered into an agreement to lease (Initial Lease) 8,629 square feet of office space at 810 Seventh Avenue, New York, NY with an option to expand an additional 8,629 square feet. The term of the Initial Lease began in March, 2010. In September 2010, the Company exercised its option right under the Initial Lease and entered into an agreement to lease (Lease Amendment) an additional 8,629 square feet of office space. The term of the Lease Amendment began in January 2011 and will expire in March 2021. In addition, the Lease Amendment extends the term of the Initial Lease to March 2021. The Initial Lease and the Lease Amendment provide for annual rent of $996,000 in 2015, $1.0 million in 2016, and $1.1 million in 2017-2020. As discussed in Note 8, the Company has sub-leased this office space.

In August 2011, Delcath Systems Limited entered into an agreement of lease for an office and manufacturing facility located in the city of Galway, Ireland. This facility is approximately 19,200 square feet and is intended to be the location of Delcath s European headquarters. The Lease is for a term of ten years, commencing August, 2011. The Lease provides for fixed annual lease amounts payable in advance in equal quarterly installments. The remaining annual lease amount is (USD conversion is based on the December 31, 2017 conversion rate): 183,179 ($143,726). Delcath Limited is also required to pay for customary building operating expenses. Delcath Limited s payment obligations and performance of the Lease are guaranteed by Delcath. The Company has sub-leased a portion of this facility.

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

In October 2016, the Company entered into a lease agreement for 95-97 Park Road in Queensbury, NY, agreeing to lease the 6,000 square feet at that location. The term began on November 1, 2016 and was effective for a two year period. The agreement provides for total annual base rent of $48,223 and will expire October 2018.

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Future minimum lease payments, net of receipts due under the terms of subleases, under all operating leases at December 31, 2017 are as follows:

(in thousands)	**Future Lease Payment**
2018	872
2019	501
2020	456
2021	281
2022	
2023	
	$ 2,110

For the years ended December 31, 2017, 2016, and 2015 rent expense totaled approximately $0.6 million, $0.5 million and $0.4 million, respectively.

Letters of Credit

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

(13) Income Taxes

There is no income tax provision for the years ended December 31, 2017, 2016 and 2015.

Income (loss) before income taxes consists of:

	Year Ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Domestic	$ (41,313)	$ (13,930)	$ (11,276)
Foreign	(3,804)	(4,040)	(3,428)

Income (loss) before taxes	$ (45,117)	$ (17,970)	$ (14,704)

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

	Year Ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Income taxes using U.S federal statutory rate	$ (15,340)	$ (6,110)	$ (4,999)
Tax Cuts and Jobs Act	143		
Nondeductible interest	6,912		
Loss on extinguishment of debt	10,174		
Loss of tax benefit of federal net operating loss carryforwards	5,067	68,795	
Loss of tax benefit of state net operating loss carryforwards	1,373	13,891	
Loss of tax benefit of federal tax credit carryforwards	324	4,023	
Amortization of gain on IP migration	767	767	767
State income taxes, net of federal benefit	(1,339)	(2,576)	380
Foreign rate differential	1,196	1,141	920
Valuation allowance	(1,423)	(75,407)	2,649
Derivative charge	(8,403)	(4,345)	(192)
Stock option exercises and cancellations	841	53	674
Research and development costs	(295)	(250)	(199)
Other	3	18	
	$	$	$

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

	Year Ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Deferred tax assets:			
Employee compensation accruals	$ 292	$ 1,386	$ 1,279
Accrued liabilities	353	343	633
Research tax credits	17	22	3,796
Other	34	55	66
Net operating losses	5,289	6,194	77,906
Total deferred tax assets	5,985	8,000	83,680

Deferred tax liabilities:

Beneficial conversion feature		906	
Other	13		
Total deferred tax liabilities	13	906	
Valuation allowance	5,972	7,094	83,680
Net deferred tax assets	$	$	$

As of December 31, 2017, 2016 and 2015, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $211.3 million, $209.3 million and $184.5 million, respectively. A significant portion of the federal amount, $210.5 million, is subject to an annual limitation of approximately $27,500 as a result of a changes in the Company s ownership in May 2003, November 2016 and multiple dates throughout 2017, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitations caused by the May 2003, November 2016 and multiple 2017 ownership changes, approximately $209.5 million of the total net operating loss

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carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $1.0 million of net operating loss carryforwards remains available to offset future federal taxable income which will expire between 2018 and 2037. In addition, the Company s state net operating losses are also subject to annual limitations that generally follow the federal Section 382 provisions (with the exception of Connecticut), adjusted for each state s respective income apportionment percentages. As of December 31, 2017 and 2016, the Company had net operating loss carryforwards for state and city income tax purposes between approximately $27.3 million and $150.3 million and between approximately $27.3 million and $153.0 million, respectively, which expire through 2037. As a result of the 382 limitations, approximately $149.0 million and $133.3 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $0.8 million and $0.8 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2017, 2016 and 2015, the Company had a net operating loss carryforward for foreign income tax purposes of $25.0 million, $21.1 million and $22.1 million, respectively, which have indefinite carryforward periods. As of December 31, 2017, 2016 and 2015, the Company had federal research and development tax credit carryforwards of approximately $4.3 million, $4.0 million and $3.8 million, respectively, which expire through 2037. As a result of the section 382 limitation, the entire tax credit carryforward is expected to expire unutilized.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company s valuation allowance decreased by approximately $1.1 million and $76.6 million in 2017 and 2016, respectively. The primary reason for the significant decrease in the valuation allowance during 2016 is due to the reduction of recognizable deferred tax assets related net operating loss and credit carryforwards resulting from the Sec. 382 ownership change. The change in valuation allowance is as follows:

(in thousands)	December 31, 2017	December 31, 2016
Beginning balance	$ 7,094	$ 83,680
Charged to costs and expenses	(1,423)	(75,407)
Charged to additional paid-in capital		(1,854)
Charged to retained earnings		1,010
Charged to other comprehensive income	301	(335)
Ending balance	$ 5,972	$ 7,094

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the Act). The Act, which is also commonly referred to as U.S. tax reform , significantly changes U.S. corporate income tax laws by, among other provisions, reducing the maximum U.S. corporate income tax rate from 35% to 21% starting in 2018. At December 31, 2017, the Company has not completed its accounting for the tax effects of enactment of the Act;

however, as described below, the Company has made a reasonable estimate of the effects on its existing deferred tax balances and the one-time transition tax. The Company is continuing to assess the impact from the Act and will record adjustments in 2018 if necessary.

During the year ended December 31, 2017, the Company reduced deferred tax assets by a provisional amount of $143,500, offset by a corresponding reduction to its valuation allowance, as a result of the re-measurement of deferred tax assets and liabilities from its 34% effective rate under existing law to the new lower statutory rate of 21%. However, the Company is still analyzing certain aspects of the Act and refining its calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts.

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

On December, 22, 2017, SAB 118 was issued due to the complexities involved in accounting for the recently enacted Act. SAB 118 requires the Company to include in its financial statements a reasonable estimate of the impact of the Act on earnings to the extent such estimate has been determined. Accordingly, the U.S. provision for income tax for 2017 is based on the reasonable estimate guidance provided by SAB 118. The Company is continuing to assess the impact from the Act and will record adjustments in 2018 if necessary.

The Company complies with the provisions of ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10 and therefore has not included a tabular rollfoward of unrecognized tax benefits. As there are no uncertain tax positions recognized, interest and penalties have not been accrued.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company s federal income tax return for the year ended December 31, 2013. The examination was completed in the third quarter of 2017 and no changes were made to the reported amounts. Accordingly, there was no effect on the financial statements as a result of the examination. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by international tax authorities or any states in connection with income taxes. The Company s New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company is no longer subject to federal and state examination for tax years ending prior to December 31, 2014; tax years ending December 31, 2014 through December 31, 2017 remain open to examination. The Republic of Ireland is the Company s only significant foreign jurisdiction. The Company is no longer subject to Ireland tax examination for tax years ending prior to December 31, 2013 (as Ireland has not initiated an audit of 2012 as of December 31, 2017); tax years ending December 31, 2013 through December 31, 2017 remain open to examination. However, the Company s tax years December 31, 1998 through December 31, 2017 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. The federal and state tax authorities can generally reduce a net

operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

Delcath recognizes interest accrued related to unrecognized tax benefits and penalties, if incurred, as a component of income tax expense.

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2017, 2016 and 2015

(14) Quarterly Financial Data (Unaudited)

Set forth below is selected quarterly financial data for each of the quarters in the years ended December 31, 2017 and 2016.

	2017 Quarters Ended			
(in thousands, except per share amounts)	**March 31**	**June 30**	**September 30**	**December 31**
Revenue	$ 743	$ 584	$ 684	$ 704
Costs and expenses	4,736	5,050	5,139	5,254
Operating loss	(4,212)	(4,601)	(4,627)	(4,725)
Net loss	(11,332)	(1,943)	(12,596)	(19,246)
Basic loss per share	43,750	1,750	4,680	375

	2016 Quarters Ended			
(in thousands, except per share amounts)	**March 31**	**June 30**	**September 30**	**December 31**
Revenue	$ 370	$ 511	$ 435	$ 676
Costs and expenses	3,721	4,232	5,047	4,882
Operating loss	(3,462)	(3,871)	(4,724)	(4,383)
Net loss	(1,813)	(6,667)	(1,004)	(8,486)
Basic loss per share	218,750	771,750	115,495	646,010

(15) Subsequent Events

As of January 25, 2018, all of the Rights issued under the December 28, 2017 Exchange Agreements discussed in more detail in Note 9 to the Company s consolidated financial statements contained in this Annual Report on Form 10-K have been exercised resulting in the issuance of 108.9 million shares.

On February 9, 2018, the Company closed a registered offering of 212,000,000 shares of common stock, 38,000,000 pre-funded warrants to purchase 38,000,000 shares of common stock and Series D warrants to purchase an aggregate of 500,000,000 shares of common stock for total gross proceeds of approximately $5.0 million. The offering was priced at $0.02 per unit with each unit comprised of one share of common stock (or one pre-funded warrant) and one common stock purchase warrant to purchase two shares, provided that, with respect to the units with pre-funded warrants $0.019 per unit shall be paid at closing and $0.001 shall be paid upon exercise of each of the pre-funded warrants. The warrants carry a five-year term from the date of initial exercisability (which is later of one year from the date of issuance and date of amendment to articles of incorporation to increase number of authorized shares of common stock) with an exercise price of $0.02 per share. The securities were offered pursuant to a registration statement on Form S-1 (File No. 333-220898) previously filed with the Securities and Exchange Commission (the SEC) and declared effective on February 7, 2018. After consummation of this offering, the Company has 434,981,824 shares of its common stock issued and outstanding.

On February 26, 2018, the Company filed a Definitive Proxy Statement on Schedule 14A seeking shareholder approval to increase its authorized shares of common stock from 500,000,000 to 1,000,000,000 in order to have sufficient authorized shares for full exercise of its recently issued Series D Warrants and for a reverse split of its common stock at a ratio of at least 1:100 but no more than 1:500, in the discretion of the Board of Directors and to grant authorization to the Board of Directors to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing (but not later than April 6, 2019).

The Company increased its authorized shares of common stock to one billion and effected a reverse split of its issued and outstanding common stock in a ratio of one-for-five hundred, effective as of May 2, 2018.

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DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2017, 2016 and 2015

On May 2, 2018, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-five hundred (1:500) split-adjusted basis. All owners of record as of the open of the OTCQB market on May 2, 2018 received one issued and outstanding share of Delcath common stock in exchange for five hundred outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-five hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 1,283	$ 3,999
Restricted cash	1,062	1,325
Accounts receivables, net	397	317
Inventories	1,250	1,248
Prepaid expenses and other current assets	382	700
Total current assets	4,374	7,589
Property, plant and equipment, net	1,099	1,298
Total assets	$ 5,473	$ 8,887
Liabilities and Stockholders Deficit		
Current liabilities		
Accounts payable	$ 5,607	$ 3,846
Accrued expenses	5,220	3,408
Current portion of convertible notes payable, net of discount	387	
Warrant liability	6,883	560
Total current liabilities	18,097	7,814
Convertible notes payable, net of current portion and debt discount	27	
Other non-current liabilities	439	395
Total liabilities	18,563	8,209
Commitments and Contingencies		
Stockholders equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively		
Common stock, $.01 par value; 1,000,000,000 shares authorized; 932,159 and 263,305 shares issued and 932,158 and 263,304 shares outstanding at June 30, 2018 and December 31, 2017, respectively*	9	3
Additional paid-in capital	311,293	325,516
Accumulated deficit	(324,305)	(324,832)
Treasury stock, at cost; 1 share at June 30, 2018 and December 31, 2017, respectively*	(51)	(51)

Accumulated other comprehensive income	(36)	42
Total stockholders (deficit) equity	(13,090)	678
Total liabilities and stockholders equity	$ 5,473	$ 8,887

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

See accompanying Notes to Condensed Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Revenue	$ 858	$ 584	$ 1,560	$ 1,327
Cost of goods sold	220	135	367	354
Gross profit	638	449	1,193	973
Operating expenses:				
Selling, general and administrative	2,641	2,532	5,007	4,947
Research and development	4,089	2,518	9,781	4,840
Total operating expenses	6,730	5,050	14,788	9,787
Operating loss	(6,092)	(4,601)	(13,595)	(8,814)
Change in fair value of the warrant liability, net	2,513	(38)	17,209	1,200
Gain on warrant extinguishment		9,613		9,613
Loss on issuance of financial instrument	(2,826)		(2,826)	
Interest expense	(248)	(6,916)	(251)	(15,282)
Other (expense) income	(5)	(1)	(10)	7
Net income (loss)	$ (6,658)	$ (1,943)	$ 527	$ (13,276)
Other comprehensive loss:				
Foreign currency translation adjustments	(36)	(30)	(78)	(8)
Comprehensive loss	$ (6,694)	$ (1,973)	$ 449	$ (13,284)
Common share data:				
Basic loss per common share*	$ (7.26)	$ (1,373)	$ 0.67	$ (15,656)
Diluted loss per common share*	$ (7.26)	$ (1,373)	$ (0.12)	$ (15,656)
Weighted average number of basic shares outstanding*	916,706	1,416	788,512	848
Weighted average number of diluted shares outstanding*	916,706	1,416	799,430	848

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

See accompanying Notes to Condensed Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Stockholders Deficit

(Unaudited)

(in thousands, except share data)

	Common Stock Issued $0.01 Par Value		Treasury Stock					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2018	263,305	$ 3	(1)	$ (51)	$ 325,516	$ (324,832)	$ 42	$ 678
Compensation income for issuance of stock options					(40)			(40)
Compensation income for issuance of restricted stock					(81)			(81)
Sale of common stock, net of expenses	668,854	6			4,204			4,210
Fair value of warrants issued					(18,306)			(18,306)
Net income						527		527
Total comprehensive loss							(78)	(78)
Balance at June 30, 2018	932,159	$ 9	(1)	$ (51)	$ 311,293	$ (324,305)	$ (36)	$ (13,090)

See accompanying Notes to Condensed Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Six months ended	
	2018	**2017**
Cash flows from operating activities:		
Net income (loss)	$ 527	$ (13,276)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation (income) expense	(40)	46
Restricted stock compensation (income) expense	(81)	64
Depreciation expense	236	127
Loss on disposal of equipment		20
Warrant liability fair value adjustment	(17,209)	(1,200)
Gain on warrant extinguishment		(9,613)
Non-cash interest income	(1)	(1)
Deferred revenue		2
Loss on issuance of financial instrument	2,826	
Debt discount amortization	238	15,277
Changes in assets and liabilities:		
Prepaid expenses and other assets	318	201
Accounts receivable	(163)	(94)
Inventories	43	(208)
Accounts payable and accrued expenses	3,985	628
Other non-current liabilities	44	(110)
Net cash used in operating activities	(9,277)	(8,137)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(39)	(276)
Net cash used in investing activities	(39)	(276)
Cash flows from financing activities:		
Net proceeds from the release of restricted cash	263	5,954
Release of restricted cash for extinguishment of Series C Warrants		7,876
Extinguishment of Series C Warrants		(7,876)
Net proceeds from convertible note debt financing	2,172	
Net proceeds from sale of stock	4,210	15
Net cash provided by financing activities	6,645	5,969

Foreign currency effects on cash and cash equivalents	(45)	(149)
Net decrease in cash and cash equivalents	(2,716)	(2,593)
Cash and cash equivalents:		
Beginning of period	3,999	4,409
End of period	$ 1,283	$ 1,816
Supplemental non-cash financing activities:		
Conversion of convertible notes	$	$ 15,831
Fair value of warrants issued	$ 23,532	$
Fair value of warrants exercised	$	$ 19,000

See accompanying Notes to Condensed Consolidated Financial Statements.

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

(1) General

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. (Delcath or the Company) as of and for the three and six months ended June 30, 2018 and 2017 should be read in conjunction with the consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017 (Annual Report), which has been filed with the Securities Exchange Commission (SEC) on March 16, 2018 and can also be found on the Company s website (www.delcath.com). In these notes the terms us , we or our refer to Delcath and its consolidated subsidiaries.

Description of Business

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

Our 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.

Our clinical development program for CHEMOSAT and 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 overall survival in mOM, and The ALIGN Trial, a registration trial for intrahepatic cholangiocarcinoma (ICC). Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

Liquidity and Operating Matters

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

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

Basis of Presentation

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

The preparation of interim financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company s results of operations, financial position and cash flows for the interim periods ended June 30, 2018 and 2017; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company s results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

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On May 2, 2018, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-five hundred (1:500) split-adjusted basis. All owners of record as of the open of the OTCQB market on May 2, 2018 received one issued and outstanding share of Delcath common stock in exchange for five hundred outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-five hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 *Summary of Significant Accounting Policies* to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K filed for the period ended December 31, 2017.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers (ASU 2014-09) that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

On January 1, 2018, the Company adopted ASU 2014-09 using the modified retrospective method and the impact was determined to be immaterial on its consolidated financial statements. The new revenue standard was applied prospectively in Delcath s condensed consolidated financial statements from January 1, 2018 forward and reported financial information for historical comparable periods will not be revised and will continue to be reported under the accounting standards in effect during those historical periods.

Delcath generates revenue from the sales of its product in Europe, where its system is commercially available under the trade name Delcath Hepatic CHEMOSAT Delivery System for Melphalan (CHEMOSAT). Revenue from product sales is generally recognized at the time of shipment to a treating center or distributor, when control of the promised goods has been transferred to our customers. When obligations or contingencies remain after the products are shipped, such as training and certifying new treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Delcath has one distribution contract with a Turkish distributor. The contract has standard provisions for termination, renewal, limited warranty and right of return. CHEMOSAT kits are delivered to the Turkish distributor as orders are received and revenue is recognized at the time of shipment to the distributor. Delcath sells directly to centers in Europe with the exception of those centers located in Turkey. Sales are processed when purchase orders are received from the hospitals and revenue is recognized at the time of shipment to the treating center.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU

2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company adopted this standard on January 1, 2018.

In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including interim periods within those fiscal years. An entity that elects early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The adoption of this standard did not have a material impact on the Company s financial statements.

Recently Issued Accounting Pronouncements

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

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

(2) Inventories

Inventories consist of the following:

(in thousands)	**June 30, 2018**	**December 31, 2017**
Raw materials	$ 339	$ 298
Work-in-process	755	721
Finished goods	156	229
Total inventories	$ 1,250	$ 1,248

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	**June 30, 2018**	**December 31, 2017**
Insurance premiums	$ 168	$ 421
Security deposit	50	50
VAT/GST receivable	37	29
Software	26	15
Financing costs	25	70
Other[1]	76	115
Total prepaid expenses and other current assets	$ 382	$ 700

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at June 30, 2018 and December 31, 2017.

(4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	**June 30, 2018**	**December 31, 2017**
Buildings and land	$ 579	$ 579
Enterprise hardware and software	1,743	1,744
Leaseholds	1,702	1,705
Equipment	979	971
Furniture	199	175
Property, plant and equipment, gross	5,202	5,174
Accumulated depreciation	(4,103)	(3,876)
Property, plant and equipment, net	$ 1,099	$ 1,298

Depreciation expense for the three and six months ended June 30, 2018 was approximately $0.1 million and $0.2 million, respectively, as compared to approximately $0.1 million and $0.1 million, respectively, for the same period in 2017.

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(5) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	June 30, 2018	December 31, 2017
Compensation, excluding taxes	$ 1,573	$ 869
Clinical trial expenses	2,304	1,124
Professional fees	314	221
Short-term portion of lease restructuring	193	209
Other[1]	836	985
Total accrued expenses	$ 5,220	$ 3,408

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at June 30, 2018 and December 31, 2017.

(6) Restructuring Expenses

In order to help reduce operating costs and more appropriately align its office space with the size of its workforce, the Company entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement (Sub-lease #1) for approximately one-half of the office space at this location (Suite 3500), resulting in a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement (Sub-lease #2) for the remaining one-half of office space at its 810 Seventh Avenue office (Suite 3505), resulting in a lease restructuring reserve of approximately $0.7 million.

The following table provides the year-to-date activity of the Company s restructuring reserves as of June 30, 2018:

(in thousands)	Lease Liability
Reserve balance at December 31, 2017	$ 604
Charges	
Payments/Utilizations	(109)
Reserve balance at June 30, 2018	$ 495

(7) Secured Convertible Notes Payable and Common Stock Purchase Warrants

On June 4, 2018, the Company entered into a Securities Purchase Agreement (the SPA) with an institutional investor pursuant to which the Company issued $3.3 million in principal face amount of senior secured convertible notes of the Company (the Notes) and related Series D Warrants (the Series D Warrants) to purchase additional shares of the Company s common stock (Common Stock). Notes in the amount of $3.3 million were issued for cash proceeds of $2.4 million with an original issue discount in the amount of $1.1 million. The Notes are secured pursuant to a Security Agreement which creates a first priority security interest in all of the personal property (other than Excluded

Collateral (as defined in the Security Agreement) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future. The Notes bear 8% interest payable quarterly in cash. Of the $3.3 million in issued Notes, $2.5 million matures in six months; the balance of $0.8 million is payable in twelve installments beginning seven (7) months after the original issuance date. Each payment shall be paid in cash or, provided that the Market Price (as defined in the SPA) is at least the conversion price of $3.00, at the option of the Company, upon ten (10) Trading Days written notice to the Holder, in free trading Common Stock at the conversion price.

In connection with the issuance of the Notes under the SPA, the Company also issued Series D Warrants. Warrant D-1 is exercisable to acquire 1.1 million shares of Common Stock at an initial exercise price of $4.00. Warrants D-2 101-113 are exercisable to acquire 13.0 million shares of Common Stock at a pre-funded exercise price of $0.01. The Company may buy back each D-2 Warrant on its date of initial exercisability so long as the Company is not in default and the applicable installment payment for each month commencing on January 4, 2019 through December 4, 2019 has been paid when due. In the event that Delcath s Market Price (as defined in the Note Agreement) is less than $3.00, the Company can only purchase back these warrants if the Notes payable are settled for cash. The provisions in the Series D Warrants required the Company to account for the warrants as derivative liabilities. The Company valued the Series D Warrants using the following inputs:

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	Warrant D-1	Warrant D-2
Expected life (in years)	5.0	5.5 - 6.5
Expected volatility	194.10%	215.0% - 389.0%
Risk-free interest rates	2.78%	2.13% - 2.30%

The Company recognized a discount to debt of $2.3 million and additional expense of $2.8 million related to the initial fair value of the Series D Warrants. The D-1 Warrants have a five-year term; the D-2 Warrants have a five-year term from initial exercisability which begins on the fifth day of each month commencing December 5, 2018, through December 5, 2019, for each of Warrant D-2-101 through 113 respectively.

(8) Stockholders Equity

Stock Issuances

Reverse Stock Split

On May 2, 2018, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-five hundred (1:500) split-adjusted basis. All owners of record as of the open of the OTCQB market on May 2, 2018 received one issued and outstanding share of Delcath common stock in exchange for five hundred outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-five hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements contained in this Quarterly Report on Form 10-Q and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

February 2018 Financing

In February 2018, the Company completed the sale of 424,000 shares of its common stock, 76,000 pre-funded warrants and the issuance of warrants to purchase 1.0 million common shares (the February 2018 Warrants) pursuant to a placement agent agreement, with net proceeds after expenses of $4.3 million. The February 2018 Warrants are exercisable one year after the anniversary date of their issuance. At June 30, 2018, the February 2018 Warrants were exercisable at $10.00 per share with 1.0 million warrants outstanding. The Company allocated an estimated fair value of $18.3 million to the February 2018 Warrants. The Company valued the February 2018 Warrants using the following inputs: exercise price of $10.00; contractual term of six years; volatility of 122.68% and risk free rate of approximately one percent. Due to certain price protection features in the agreement, the February 2018 Warrants were accounted for as a derivative liability at issuance and will be subsequently marked to market through the statement of operations.

Stock Incentive Plans

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

For the three and six months ended June 30, 2018, the Company recognized compensation income of $47,000 and $40,000 relating to stock options granted to employees. For the same period in 2017, the Company recognized compensation expense of approximately $24,000 and $46,000 respectively.

For the three and six months ended June 30, 2018, the Company recognized compensation income of $94,000 and $81,000 relating to restricted stock granted to employees. For the same period in 2017, the Company recognized compensation expense of approximately $6,000 and $100,000, respectively.

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(9) Fair Value Measurements

Derivative Warrant Liability

For the three and six months ended June 30, 2018, the Company recorded derivative warrant expense of $2.5 million and $17.2 million, respectively. The resulting derivative warrant liabilities totaled $6.9 million at June 30, 2018. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at June 30, 2018 and December 31, 2017 was determined by using option pricing models with the following assumptions:

	June 30, 2018	December 31, 2017
Expected life (in years)	0.33 - 6.40	0.82 - 4.88
Expected volatility	132.69% - 372.0%	130.88% - 266.92%
Risk-free interest rates	1.99% -2.92%	1.68% - 2.06%

The table below presents the Company s assets and liabilities measured at fair value on a recurring basis as of June 30, 2018, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

	Assets and Liabilities Measured at Fair Value on a Recurring Basis			
(in thousands)	Level 1	Level 2	Level 3	Balance at June 30, 2018
Liabilities				
Derivative instrument liabilities	$	$	$ 6,883	$ 6,883

For the periods ended June 30, 2018 and 2017, there were no transfers in or out of Level 1, 2 or 3 inputs.

The table below presents the activity within Level 3 of the fair value hierarchy for the six months ended June 30, 2018:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2017	$ 560
Fair value of warrants issued	23,532
Fair value of warrants exercised	
Total change in the liability included in earnings	(17,209)
Balance at June 30, 2018	$ 6,883

(10) Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath s common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

	June 30,	
(in thousands, except share data)	**2018**	**2017**
Net income (loss) - basic	$ 527	$ (13,276)
Adjustment for gain on warrant income	(619)	
Net loss - diluted	$ (92)	$ (13,276)
Weighted average shares outstanding - basic	788,512	848
Weighted average shares outstanding - diluted	799,430	848
Net income (loss) per share - basic	$ 0.67	$ (15,656)
Net income (loss) per share - diluted	$ (0.12)	$ (15,656)

The following potentially dilutive securities were excluded from the computation of earnings per share as of June 30, 2018 and June 30, 2017 because their effects would be anti-dilutive:

	June 30, 2018	**June 30, 2017**
Stock options		55,846
Unvested restricted shares		101,294
Warrants	2,116,296	36,848
Assumed conversion of convertible notes	1,116,255	
Total	3,232,551	193,988

(11) Taxes

As discussed in Note 13 *Income Taxes* of the Company s Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

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The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company s federal income tax return for the year ended December 31, 2013. The examination was completed in the third quarter of 2017 and no changes were made to the reported amounts. Accordingly, there was no effect on the financial statements as a result of the examination. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations. Additional information regarding the statutes of limitations can be found in Note 13 *Income Taxes* of the Company s Annual Report.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the Tax Act) was enacted into law and the new legislation contains several key tax provisions that affected us, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. We were required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring our U.S. deferred tax assets and liabilities as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting of deferred tax re-measurements and the transition tax to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions. As of June 30, 2018, a SAB 118 measurement period adjustment has not been recorded, as the Company is continuing to assess the impact from the Tax Act and will record adjustments in 2018 if necessary.

In October 2016, the Financial Accounting Standards Board (FASB) issued accounting standards update 2016-16 which simplifies the income tax consequences of intra-entity transfers other than inventory. Prior to ASU 2016-16, GAAP prohibited the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. ASU 2016-16 eliminates this prohibition for intra-entity transfers of assets other than inventory but retain the prohibition for intra-entity transfers of inventory. This standard is effective for public entities for fiscal years beginning after December 15, 2017. The Company adopted ASU 2016-16, effective on January 1, 2018. As a result of adoption, the Company recognized a $834 decrease to its net operating loss deferred tax assets, offset by a $834 decrease to the corresponding valuation allowance.

(12) Subsequent Events

Additional Secured Convertible Note

On July 20, 2018, the Company entered into a Securities Purchase Agreement with Discover Growth Fund, LLC for the remaining Notes and Warrants in proportionate amounts to those issued in the June 4, 2018 transaction which is discussed in Note 7, in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act and Rule 506(b) promulgated thereunder, and received gross proceeds of $1,600,000.

Warrant Amendments

On July 20, 2018, the Company and Discover Growth Fund amended the June 4, 2018 Securities Purchase Agreement to delay the Company s registration obligation, and amended the Warrants issued thereunder so that they are exercisable as of the amendment date and the Company may redeem them at any time the Notes are no longer

outstanding as well as to amend the Fundamental Transaction clause in each which result in the Series D Warrants no longer being treated as a liability as of the date of the amendment.

Litigation

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the Suit). The Suit alleges breaches by the Company of Hudson Bay s rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. The Company denies any liability with respect to the claims set forth in the Suit.

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Rights Offering

On August 3, 2018, our registration statement on Form S-1 was declared effective by the SEC. Pursuant to our rights offering, we have distributed to holders of our common stock, and holders of certain of our instruments convertible or exchangeable into our common stock, on an as converted basis, non-transferrable subscription rights (500 shares per right) to purchase up to an aggregate of 28,571,429 shares of our common stock. Holders of our common stock will receive one subscription right for each share of common stock owned and holders of certain of our instruments convertible or exchangeable into our common stock will receive one subscription right for each share of common stock they would own upon full conversion of certain of our instruments convertible or exercisable into our common stock owned and settled by, 4:00 p.m., New York City time, on August 3, 2018; provided, that, the rights may only be exercised for a maximum of the lesser of 28,571,429 shares or $50.0 million of subscription proceeds.

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Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

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

Our 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.

Our clinical development program for CHEMOSAT and 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 overall survival in mOM and the ALIGN Trial, a registration trial for intrahepatic cholangiocarcinoma (ICC). Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

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.

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

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing adequate reimbursement for the procedure is strongest. In 2015, national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that 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.

Our Ability to Continue as a Going Concern

The notes contained in our Annual Report on Form 10-K for year ended December 31, 2017 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 include a disclosure describing the existence of

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conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our consolidated financial statements as of December 31, 2017 have been prepared under the assumption that we will continue as a going concern. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our former independent registered public accounting firm has issued its report dated March 16, 2018 in connection with the audit of our consolidated financial statements as of December 31, 2017 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

Liquidity and Capital Resources (for the year ended December 31, 2017)

The Company s future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming year. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath s future liquidity and capital requirements will depend on numerous factors, including the progress of clinical trials and research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At December 31, 2017, the Company had cash and cash equivalents totaling $4.0 million, as compared to cash and cash equivalents totaling $4.4 million at December 31, 2016. During the year ended December 31, 2017, the Company used $15.4 million of cash for its operating activities, which compares to $14.2 million used for operating activities during the year ended December 31, 2016. The increase of $1.2 million is primarily driven by an increase in operating expenses primarily related to the Company s clinical trial effort discussed in the Business Overview section. The Company believes it has sufficient capital to fund its operating activities through May 2018.

Our consolidated financial statements as of December 31, 2017 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because Delcath s business does not generate positive cash flow from operating activities, the Company will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to Ocular Melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either selling shares of Delcath s capital stock, borrowing money or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of its business. Further, the Company s assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the timing, scope, focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, and public offerings in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016 and 2018, including registered direct

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offerings in 2007, 2009 and 2013, at the market equity offering programs in 2012 and 2013, and by a private placement of convertible notes in 2016. For a detailed discussion of the Company s various sales of securities see Note 10 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $71.8 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company is not currently eligible to use its Form S-3.

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

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

On November 6, 2017, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-three hundred and fifty (1:350) split-adjusted basis. All owners of record as of the open of the OTCQB market on November 6, 2017 received one issued and outstanding share of Delcath common stock in exchange for three hundred and fifty issued and outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-three hundred and fifty exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

On February 9, 2018, the Company closed a registered offering of 212.0 million shares of common stock, 38.0 million pre-funded warrants to purchase 38.0 million shares of common stock and Series D warrants to purchase an aggregate of 500.0 million shares of common stock for total gross proceeds of approximately $5.0 million. The offering was priced at $0.02 per unit with each unit comprised of one share of common stock (or one pre-funded warrant) and one common stock purchase warrant to purchase two shares, provided that, with respect to the units with pre-funded warrants $0.019 per unit shall be paid at closing and $0.001 shall be paid upon exercise of each of the pre-funded warrants.

On February 26, 2018, the Company filed a Definitive Proxy Statement on Schedule 14A seeking shareholder approval to increase its authorized shares of common stock from 500,000,000 to 1,000,000,000 in order to have sufficient authorized shares for full exercise of the recently issued Series D warrants and for a reverse split of its common stock in a ratio of at least 1:100 but no more than 1:500. There is no assurance that the Company will receive

shareholder approval for these two proposals, and will not be able to raise further funds or provide for exercise of our Series D warrants without these approved proposals. As of May 2, 2018, we had effected a 1-for-500 reverse stock split.

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Contractual Obligations, Commercial Commitments and Off-Balance Sheet Arrangements

The Company is obligated to make future payments under various operating lease agreements. The following table provides a summary of significant contractual obligations at December 31, 2017:

		Payments Due by Period			
(in millions)	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Activities:					
Future minimum lease payments, net of receipts due under subleases	$ 2.1	$ 0.9	$ 1.2	$	$

Delcath s operating lease obligations at December 31, 2017 include: the annual rent for office space at 1633 Broadway, New York, New York, which will expire in March 2019; the annual rent under the lease for office space at 810 Seventh Avenue, New York, New York, which will expire in March 2021 and of which a certain amount of expense has been offset by two sub-leases; the annual rent under the lease for a facility in Queensbury, New York, which will expire in October 2018; and the annual rent for a facility in Galway, Ireland, which will expire in August 2021 and of which a certain amount of expense has been offset by a sub-lease. See Part I, Item 2, Properties and Notes 8 and 12 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K.

Future Capital Needs; Additional Future Funding

The Company s future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve consistent profitability. The Company believes that it has adequate resources to fund operations through May 2018. Additional working capital will be required to continue operations. There can be no assurance that such working capital will be available on acceptable terms, if at all.

Results of Operations for the Year Ended December 31, 2017; Comparisons of Results of the Years Ended December 31, 2016 and 2015

Revenue

The Company recorded approximately $2.7 million in total revenue during the year ended December 31, 2017. During the same period in 2016, Delcath recorded $2.0 million in total revenue related to product sales. The year over year increase is a result of greater product sales in 2017 as Delcath continues to see increased market acceptance of its product in the EU, particularly in Germany where the establishment of the ZE code has contributed to increased treatments.

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

Cost of Goods Sold

During the year ended December 31, 2017, the Company recognized cost of goods sold of approximately $0.7 million related to product revenue of $2.7 million.

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

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

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

Selling, General and Administrative Expenses

For the year ended December 31, 2017, selling, general and administrative expenses increased to $9.7 million from $9.4 million for the year ended December 31, 2016. The increase is due primarily to an increase in Delaware corporate taxes, in independent audit fees due to additional testing over the Company s internal control over financial reporting and an increase in costs associated with the Company s shareholder meetings as a result of the efforts to secure approval for a reverse stock split.

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

Research and Development Expenses

For the year ended December 31, 2017, research and development expenses increased to $10.5 million from $8.4 million for the year ended December 31, 2016. The increase of $2.0 million is primarily due to the ongoing efforts of the FOCUS Trial which is discussed in further detail in the *Current Clinical Development Program* section above.

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

Change in fair value of derivative liability

For the year ended December 31, 2017, derivative instrument income increased to $15.1 million from $12.8 million for the year ended December 31, 2016. The increase of $2.3 million is due to the decline in the stock price from the time of the initial $14.4 million valuation of the November 2017 Warrants. The subsequent valuation at December 31, 2017 resulted in income of approximately $13.8 million as discussed in more detail in Note 11 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K.

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

Gain on warrant extinguishment

As discussed further in Note 9 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K., the Company recorded a $9.6 million gain related to the extinguishment of the June 2016 Series C Warrants that were issued as part of the private placement of Senior Secured Convertible Notes.

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Loss on debt settlements and extinguishments

As discussed further in Notes 9 and 10 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K, the Company recorded a $29.9 million loss on debt settlements and extinguishments related to the following transactions:

1. July 2, 2017 issuance of Series A Preferred Shares that resulted in a $1.0 million loss on debt settlement

2. August 28, 2017 restructuring agreement that resulted in a $1.9 million loss on debt settlement

3. November 6, 2017 warrant exchange pursuant to October 10, 2017 amendment to the August 28, 2017 restructuring agreement that resulted in a $2.3 million loss on debt extinguishment

4. November 15, 2017 exchange agreement and related warrant issuance that resulted in a $21.0 million loss on debt extinguishment

5. December 28, 2017 exchange agreement that resulted in a $3.7 million loss on debt extinguishment

Other Income/Expense and Interest Expense

Other income (expense) increase is related to foreign currency exchange gains and losses.

Interest expense is related to:

1. the restructuring lease liability discussed in Note 8 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K;

2. the amortization of debt discounts and debt issuance costs discussed in Note 9 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K; and

3. original issuance discounts related to the issuance of Series C preferred stock discussed in Note 10 of the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K.

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

Net Loss

The Company had a net loss for the year ended December 31, 2017 of $45.1 million, an increase of $27.1 million, or 151.1%, compared to the net loss for the same period in 2016. This increase is primarily due to a $7.4 million increase in interest expense primarily related to the amortization of debt discounts, a $29.9 million loss on settlements and extinguishments of the convertible note debt, both non-cash items, and both discussed further in Note 9 of the Company s consolidated financial statements contained in this Annual Report on Form 10-K, and a $2.3 million increase in operating expenses primarily related to increased investment in clinical trial initiatives. This was offset by

a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants and a $2.3 million increase in the change in the fair value of the warrant liability, both non-cash items, and a $0.6 million improvement in gross profit due to increased sales.

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

Income Taxes

The Company has not recorded a provision for income taxes in the years ending December 31, 2017, 2016, and 2015, respectively, due to being in a net tax operating loss position for each of those years.

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On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the Act) was enacted into law and the new legislation contains several key tax provisions that affected the Company, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. The Company is required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring its U.S. deferred tax assets and liabilities as well as reassessing the net realizability of deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allows the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next twelve months, the Company considers the accounting of deferred tax re-measurements and the transition tax to be incomplete due to the forthcoming guidance and its ongoing analysis of final year-end data and tax positions. However, the Company was able to determine a provisional amount of $143,500 (offset by valuation allowance) and $0, respectively, related to the deferred tax re-measurement and one-time transition tax (additional detail is provided in Note 13 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K). We expect to complete the analysis within the measurement period in accordance with SAB 118.

Application of Critical Accounting Policies

The Company s consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the consolidated financial statements. A summary of those significant accounting policies can be found in Note 3 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-K.

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

On January 1, 2012, Delcath Systems, Inc. sold a portion of its intellectual property to Delcath Holdings Limited resulting in a taxable gain of $15.8 million in the U.S. based on the fair market value of the intangible that was transferred. The arms-length price, which was determined in accordance with Section 482 of the Internal Revenue Code, is a significant accounting estimate. The gain is deferred under U.S. GAAP principles until the asset is sold outside of the consolidated financial statements. The remaining deferred gain on the intercompany sale of intangible assets is $2.0 million, $4.4 million and $6.7 million as of December 31, 2017, December 31, 2016 and December 31, 2015, respectively.

The Company has adopted the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders requisite service

period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to

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non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity s own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity s own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety.

The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 9 to the Company s audited consolidated financial statements contained in this Annual Report on Form 10-Kfor assets and liabilities the Company has evaluated under ASC 820.

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Management s Discussion and Analysis For the Three and Six Months Ended June 30, 2018

Results of Operations for the three and six months ended June 30, 2018; Comparisons of Results of Operations for the three and six months ended June 30, 2017

Three months ended June 30, 2018 and June 30, 2017

Revenue

The Company recorded approximately $0.9 million in revenue related to product sales for the three months ended June 30, 2018 and $0.6 million in revenue related to product sales for the three months ended June 30, 2017. Although sales remain modest, the increase is driven by the establishment of ZE diagnostic-related group reimbursement for CHEMOSAT procedures in Germany.

Cost of Goods Sold

For the three months ended June 30, 2018, the Company recorded cost of goods sold of approximately $0.2 million compared to $0.1 million for the three months ended June 30, 2017. The increase in cost of goods is commensurable to the slight increase in sales quarter over quarter.

Selling, General and Administrative Expenses

For the three month period ended June 30, 2018 and 2017, selling, general and administrative expenses were $2.6 million and $2.5 million, respectively. The slight increase for the three months ended June 30, 2018 is related to decreased production and adjustments to overhead allocations.

Research and Development Expenses

For the three month period ended June 30, 2018 and 2017, research and development expenses increased to $4.1 million from $2.5 million, primarily due to the ongoing accrual of the Company s Phase 3 FOCUS trial which is discussed in further detail in the *Current Clinical Development Program* section above.

Other Income/Expense and Interest Income/Expense

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

Interest expense is related to:

1. the restructuring lease liability discussed in Note 6 of the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q; and

2. the amortization of debt discounts discussed in Note 7 of the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

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

Change in the Fair Value of the Warrant Liability

For the three months ended June 30, 2018 the change in the fair value of the warrant liability adjusted to income of $2.5 million versus expense of $0.04 million for the three months ended June 30, 2017. The increase of $2.6 million is due to the mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 9 to the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Net Loss

The Company recorded net loss for the three months ended June 30, 2018, of $6.7 million, an increase of $4.7 million, or 242.6%, compared to a net loss of $1.9 million for the same period in 2017. This increase in net loss is primarily due to a $6.7 million decrease in interest expense primarily related to the amortization of debt discounts related to convertible notes that were fully satisfied in 2017, and a $2.6 million increase in the change in the fair value of the warrant liability, both non-cash items. Additionally, there was a $1.7 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

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Six months ended June 30, 2018 and June 30, 2017

Revenue

The Company recorded approximately $1.6 million in revenue related to product sales for the six months ended June 30, 2018 and $1.3 million in revenue related to product sales for the six months ended June 30, 2017. Although sales remain modest, the increase is driven by the establishment of ZE diagnostic-related group reimbursement for CHEMOSAT procedures in Germany.

Cost of Goods Sold

For the six months ended June 30, 2018, the Company recorded cost of goods sold of approximately $0.4 million compared to $0.4 million for the six months ended June 30, 2017.

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Selling, General and Administrative Expenses

For the six months ended June 30, 2018 the Company recorded selling, general and administrative expenses of approximately $5.0 million compared to $4.9 million for the same period in 2017. The slight increase for the three months ended June 30, 2018 is related to decreased production and adjustments to overhead allocations.

Research and Development Expenses

For the six months ended June 30, 2018 and 2017, research and development expenses increased to $9.8 million from $4.8 million, primarily due to the ongoing enrollment of our Phase 3 trial during 2018 which is discussed in further detail in the *Current Clinical Development Program* section above.

Other Income/Expense and Interest Expense

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

Interest expense is related to:

1. the restructuring lease liability discussed in Note 6 of the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q; and

2. the amortization of debt discounts discussed in Note 7 of the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

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

Derivative Instrument Income

For the six months ended June 30, 2018 derivative instrument income increased to $17.2 million from $1.2 million for the six months ended June 30, 2017. The increase of $16.0 million is due to the extinguishment of the Series C Warrants during the six months ended June 30, 2017, the issuance of Series D Warrants during the six months ended June 30, 2018 and the related mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 7 and Note 9 to the Company s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Net Income

The Company recorded net income for the six months ended June 30, 2018, of $0.5 million, an increase of $13.8 million, or 104.0%, compared to a net loss of $13.3 million for the same period in 2017. This increase in net income is primarily due to a $15.0 million decrease in interest expense related to the amortization of debt discounts, offset by a reduction of prior year s gain of $9.6 million on the extinguishment of the June 2016 Series C Warrants. Additionally, there was a $5.0 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives, offset by $0.2 million increase in gross profit and a $16.0 million increase in the change in the fair value of the warrant liability, a non-cash item.

Liquidity and Capital Resources

The Company s capital resources as of June 30, 2018 are not sufficient to fund planned operations during 2018. The Company will need to raise $20-25 million of outside capital under structures available to it including debt and/or equity offerings this year. If these sources do not provide the capital necessary to fund the Company s operations, the Company will need to curtail certain aspects of its operations or consider other means of obtaining additional financing, although there is no guarantee that the Company could obtain the financing necessary to continue its operations.

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The Company s future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming years. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its clinical and operating activities. Delcath s future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At June 30, 2018, the Company had cash and cash equivalents totaling $1.3 million, as compared to cash and cash equivalents totaling $4.0 million at December 31, 2017 and $1.8 million at June 30, 2017. During the six months ended June 30, 2018 and June 30, 2017, the Company used $9.3 million and $8.1 million respectively, of cash in its operating activities. The Company believes that its capital resources are adequate to fund its operating activities through August 2018.

Our consolidated financial statements as of June 30, 2018 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because Delcath s business does not generate positive cash flow from operating activities, the Company will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to Ocular Melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath s capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of its business. Further, the Company s assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the timing, scope, focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, and public offerings in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016 and 2018, including registered direct offerings in 2007, 2009 and 2013, at the market equity offering programs in 2012 and 2013, and by the private placement of convertible notes in 2016 and 2018. For a detailed discussion of the Company s various sales of securities see Note 8 to the Company s financial statements contained in this Quarterly Report on Form 10-Q.

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

Application of Critical Accounting Policies

The Company s financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 3 to the Company s audited financial statements contained in the 2017 Annual Report on Form 10-K.

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Delcath Systems, Inc.

PRELIMINARY PROSPECTUS

August , 2018

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PART II

Item 13. Other expenses of issuance and distribution

The following table sets forth the costs and expenses, other than placement agent fees to be paid by us in connection with the sale of common shares being registered hereby. All amounts are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	$
FINRA filing fee	
Legal fees and expenses	50,000
Accounting fees and expenses	40,000
Printing and engraving expenses	5,000
Transfer agent and registrar fees and expenses	10,000
Other expenses	20,000
Total	$125,000

Item 14. Indemnification of directors and officers

Section 102(b)(7) of the DGCL allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the director breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides for this limitation of liability.

Section 145 of the DGCL, or Section 145, provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation s best interests, provided that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director has actually and reasonably incurred.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

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Our amended and restated bylaws provides that we must indemnify our directors and officers to the fullest extent permitted by the DGCL and must also pay expenses incurred in defending any such proceeding in advance of its final disposition upon delivery of an undertaking, by or on behalf of an indemnified person, to repay all amounts so advanced if it should be determined ultimately that such person is not entitled to be indemnified.

We have entered into indemnification agreements with certain of our executive officers and directors pursuant to which have agreed to indemnify such persons against all expenses and liabilities incurred or paid by such person in connection with any proceeding arising from the fact that such person is or was an officer or director of our company, and to advance expenses as incurred by or on behalf of such person in connection therewith.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, provision of our certificate of incorporation, our bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

We maintain standard policies of insurance that provide coverage (1) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (2) to us with respect to indemnification payments that we may make to such directors and officers.

The proposed form of Placement Agency Agreement to be filed as Exhibit 1.1 to this Registration Statement will provide for indemnification of our directors and officers by the placement agent party thereto against certain liabilities. See Item 17. Undertakings for a description of the SEC s position regarding such indemnification provisions.

Item 15. Recent sales of unregistered securities

On June 6, 2016, the Company completed a private placement, exempt for registration purposes under Section 4(a)(2) of the Securities Act, of $35 million aggregate principal amount of senior secured convertible notes (the Notes) pursuant to a Securities Purchase Agreement dated June 6, 2016 (the SPA) between the Company and certain institutional investors as set forth in the Schedule of Buyers attached to the SPA, as described in the Company s Form 8-K filed with the Securities and Exchange Commission on June 7, 2016.

The Notes were issued at an 8 percent original issue discount to the principal amount of Notes (a purchase price of $920 for each $1,000 principal amount of Notes and related warrants) for aggregate proceeds of $32.2 million. The Notes do not bear any ordinary interest and provide that the Company will repay the principal amount of the Notes in equal monthly installments beginning seven months after the original date of issuance.

The Company also issued warrants to purchase 6.8 million additional shares of common stock to such institutional investors concurrently with the issuance of the Notes. The Company repurchased all of such warrants for cash, effective as of March 31, 2017.

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series A Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series A Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series A Preferred Stock). On July 2, 2017, we entered into an exchange agreement (the Exchange) with one of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the Series A Preferred Shares). The Exchange was made in

reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Shares were entitled to the whole number of votes equal to $4.2 million divided by $1,288.00 (the closing bid price on June 13, 2016, the date of issuance of the Notes as adjusted for the reverse stock split effected in July 2016,) or 3,261 votes. The Series A Preferred Stock had no dividend, liquidation or other preferential rights to our common stock, and each share of Series A Preferred Stock was redeemed for the amount of $0.01 on August 28, 2017.

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On July 11, 2017, we entered into an Amended and Restated Securities Purchase Agreement (the Amended Purchase Agreement) with certain institutional investors for the sale by the Company of 2,360 shares of Series B Preferred Stock (the Series B Preferred Stock) at a purchase price of $1,000 per share, in a private placement. The aggregate gross proceeds for the sale of the Series B Preferred Stock is $2.0 million. The Company intends to use the proceeds from the transaction for general corporate purposes. The restricted shares of Series B Preferred Stock have no registration rights and thus will not be eligible for legend removal for a period of at least six months from the date of closing. This Amended Purchase Agreement amends the July 5, 2017 Securities Purchase Agreement (the Purchase Agreement) into which we entered with certain institutional investors (the Investors) for the sale by the Company of 2,360 shares of Series B Preferred Stock in a registered direct offering. The Series B Preferred Stock shall be entitled to the whole number of votes equal to $2.0 million divided by $65.35 (the closing bid price on July 5, 2017, the date of sale of the Series B Preferred Stock), or 30,607 votes. The Series B Preferred Stock has no liquidation or other rights which are preferential to our common stock. The Series B Preferred Stock was redeemed for $2,360,000 in August 2017.

On August 28, 2017, the Company entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the SPA. As of the date the Agreement was entered into, the Investor held $11,444,637 aggregate principal amount of Notes of which there was $10,092,857 aggregate Restricted Principal, (as defined in the Notes) of Notes (the Restricted Notes), secured by such aggregate cash amount held in a collateral account of the Company in the same amount (the Restricted Cash) and (y) $1,351,780 principal of Notes (the Unrestricted Notes), (ii) 4,200 shares of Series A Preferred Stock and (iii) 2,006 shares of Series B Convertible Preferred Stock.

Pursuant to the Agreement, (a) on the date thereof the Company and the Investor took the following actions (the Initial Restructuring): (i) the Investor released restrictions on $1,650,000 of Restricted Cash (the Initial Release), (ii) the Investor consented to the use of additional Restricted Cash to effect redemptions of the Series A Preferred Shares and the Series B Preferred Shares, (iii) the Investor cancelled $1,200,000 aggregate principal of the Notes (such portion of the Notes, the Cancellation Note), (iv) the Company redeemed all the Series A Preferred Shares outstanding for a cash payment to the Investor of $4.20 and (v) the Company redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 and (b) upon the consummation of a reverse stock split of our Common Stock of at least twenty to one (the Reverse Stock Split Event , and such date, the Reverse Stock Split Date) by September 15, 2017, the Company and the Investor shall have taken the following actions (the Additional Restructuring , and together with the Initial Restructuring, the Restructuring): (i) the Investor shall consent to the use of Restricted Cash to effect redemptions of $4,000,000 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Redemption Notes), (ii) the Company shall redeem the Redemption Notes for a redemption price of $6,436,852.80 (the Redemption Price) and (iii) the Company shall exchange (the Exchange), pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, $2,436,852.80 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Exchange Notes , and together with the Redemption Notes, the Restructured Notes) for new warrants to purchase 114,286 shares of its Common Stock (the New Warrants , as exercised, the New Warrant Shares). The New Warrants expire on the 42 month anniversary of the date of issuance and bear an exercise price of $122.50 per share (which shall be adjusted to the new lower purchase price per share if there is a subsequent down round financing). The Investor, in lieu of an exercise of the New Warrants pursuant to a cash payment of the aggregate exercise price of the number of New Warrants being exercised, may exercise the New Warrants, in whole or in part, by electing instead to receive upon such exercise two shares and one hundred and twenty-five thousandths of a share of the Company s Common Stock for each Warrant Share exercised pursuant to this provision. The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act) and Rule 144(d)(3)(ii) of the 1933 Act. As a result of not having effected a reverse stock split by September 15, 2017, the Additional Restructuring did not occur.

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Amendment to Restructuring Agreement

As a result of the lack of requisite approval by Delcath stockholders for the Company s proposed reverse stock split, the parties and the two investors in the Notes entered into an amendment to the August restructuring agreement on October 10, 2017 as follows: (i) on the date that the Company effects a reverse split of its common stock, (x) the Company will exchange, pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, an aggregate principal amount of those notes equal to $279,015 for new warrants to purchase an aggregate of 127,551 shares of Common Stock, and the Company shall redeem all the Series C Preferred Shares then outstanding for a cash payment of $590,000 and (ii) upon the initial consummation, on or prior to December 15, 2017, by the Company of the offering contemplated by the registration statement on Form S-1 that was filed with the SEC on October 11, 2017 the following shall occur: (i) pursuant to Section 3(b) of the Restricted Notes, the Company shall be deemed (as adjusted downward by the Black-Scholes value of the warrants being issued in this offering) to have automatically, and irrevocably, adjusted the conversion price of the Notes to 200% of the purchase price of a share of our common stock in the offering contemplated by the registration statement, (ii) the maturity date (as defined in the notes) shall automatically be extended to the earlier to occur of (x) the first anniversary of the date of consummation of the offering contemplated by the registration statement and (y) December 30, 2018, (iii) until the earlier of (x) this maturity date and (y) the 75th calendar day after the date of consummation of the offering contemplated by the registration statement, all installments to be made under the notes shall be deemed automatically deferred with no conversions during that 75 day period, (iv) the Company agreed to redeem any portion of the outstanding notes at any time requested by either investor thereto with $7.3 million in cash to be reduced by $0.6 million to redeem the Series C Preferred Stock remaining in the restricted accounts with respect to the 2016 convertible notes and (v) the conversion floor price on the notes is $0.05 and not subject to adjustments.

On September 21, 2017, we entered into a securities purchase agreement (the SPA) with two of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $0.5 million aggregate purchase price for 590 shares of Series C Preferred Stock (the Series C Preferred Shares). The purchase of the Series C Preferred Stock is being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended. The Series C Preferred Shares shall be entitled to 1,484,061 votes and may only vote on approval of a reverse split of our outstanding common stock. The Series C Preferred Stock has no dividend, liquidation or other preferential rights to our common stock, and each share of Series C Preferred Stock shall be redeemable for the amount of $1,000.00, payable in cash, per share at our written election, and must be redeemed by us no later than December 21, 2017. The Series C Preferred Stock was redeemed for $590,000 in November 2017.

On November 15, 2017, Delcath Systems, Inc. (the Company) entered into exchange agreements (Exchange Agreements) with each of the two investors from its June 2016 private placement of senior secured convertible notes as contemplated by that certain Securities Purchase Agreement, dated June 6, 2016, by and among the Company and such investors. As of November 15, 2017, those investors held $11,157,970 aggregate principal amount of investor notes (the Investor Notes), including (a) such aggregate principal amount of the Investor Notes as set forth on the signature page of the Investor hereto that does not include Restricted Principal as of the date hereof and all accrued and unpaid interest under the Investor Notes (such portion of the Investor Notes, the Unrestricted Investor Notes) and such aggregate principal amount of the Investor Notes as set forth on the signature page of the investors hereto that solely consists of Restricted Principal as of the date hereof (such portion of the Investor Notes, the Restricted Investor Notes).

On November 15, 2017, the Company authorized a new series of senior secured convertible notes of the Company, in the aggregate original principal amount as set forth above (the Exchange Notes), which Exchange Notes shall be convertible into shares of Common Stock in accordance with the terms of the Exchange Notes. Subject to the terms

and conditions of the Exchange Agreements, the Company and the investors exchanged (the Exchange) the Unrestricted Investor Notes for (a) $10,562,425 aggregate principal amount of the Exchange

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Notes (the New Notes , and the shares of Common Stock issuable pursuant to the terms of the New Notes, including, without limitation, upon conversion or otherwise, collectively, the New Conversion Shares) and (b) warrants to purchase an aggregate of 7,000,000 shares of Common Stock (the New Warrants , as exercised, the New Warrant Shares).

The New Conversion Shares and the New Warrant Shares are collectively referred to herein as the New Underlying Securities and, together with the New Notes and the New Warrants, the New Securities .

The New Notes, which were satisfied in full on December 28, 2017, bore the following terms:

- The New Notes did not bear interest except upon the occurrence of an event of default upon which the interest rate is 15% per annum.

- The initial conversion price was $1.50 per share for an optional conversion and at any time, an investor could have instead engaged in an alternate conversion for which the conversion price is 82% (75% if an event of default) of the lowest volume weighted average price for the Company s common stock on the three trading days prior to and including the date of the conversion. All conversions attributable to the Restricted Notes could have been converted at the lower of the optional conversion price and the alternate conversion price, then in effect.

- The obligation to prepay the Notes was extended to March 31, 2018, except in the case of an event of default or change in control.

- Assuming equity conditions as stated in the New Notes are met, the investors would consent to release cash to the Company from the existing controlled accounts upon conversion of the New Notes.

- The New Notes contained provisions waiving Section 8 of the Restricted Investor Notes, including, without limitation, any requirements for the Company to effect installment conversions or redemptions.

- The New Notes contained customary and usual terms including but not limited to, events of default upon failure to trade on an eligible market, failure to timely deliver shares upon conversion, failure to maintain converted share reserve, for conversions, failure to make payments thereunder when due, failure to remove legends, cross defaults to other indebtedness, bankruptcy and the like, and any material adverse effect in the Company s financial condition, as well as remedies and negative covenants substantially similar to those in the Investor Notes.

The New Warrants bear the following terms:

- The Warrants will be exercisable for five years from the date of issuance.

The initial exercise price of the warrants is 115% of the closing bid price of the Company s common stock as of the trading day ended immediately prior to the time of execution of the Exchange Agreement.

The Warrants contain full antidilution ratchet protection from lowered price securities issuances subsequent to the date of issuance for six months from the date of issuance and most favored nations protection for a year from the date of issuance.

The Warrants are exercisable on a cashless basis to the extent at any time commencing on the one year anniversary of the date of issuance the issuance of underlying securities is not covered by an effective registration statement.

To the extent the investors elect to apply any amounts in their controlled accounts to the balances of the New Notes, the number of shares into which the applicable New Warrant is exercisable shall be reduced by a formula set forth in the New Warrants.

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On December 28, 2017, we entered into exchange agreements (collectively, Exchange Agreements), each by and between us and an investor from its June 2016 private placement of senior secured convertible notes (as further exchanged, the Notes) originally issued pursuant to that certain Securities Purchase Agreement, dated June 6, 2016, by and among us and such investors. Pursuant to the Exchange Agreements, we (i) extinguished our remaining $3,027,408 in outstanding obligations under the Notes in full, (ii) obtained a release of restrictions on $2,046,897.66 in restricted cash held in our control accounts, (iii) issued to the investors shares (the Shares) of our common stock (or rights (Rights) to receive common stock to the extent such issuance of Shares would otherwise result in the beneficial ownership by any such investor of more than 4.9% or 9.9% of our issued and outstanding stock), as applicable, of an aggregate of 123,708,735 shares of our common stock (in each case, subject to trading restrictions set forth in leak out agreements we separately entered into with each investor (collectively, the Leak-Out Agreements)) and (iv) a cash payment to the investors of $829,830.54 from the restricted cash held in our control accounts. The number of shares of our issued and outstanding common stock immediately following issuance of the initial Shares to the investors is 114,054,852.

The Rights may be exercised in whole or in part by an investor, without payment of additional consideration, at any time an investor would not beneficially own more than 4.9% or 9.9% (as set forth in the applicable Exchange Agreement) of our common stock (along with any shares of our common stock owned by any Attribution Parties) outstanding immediately after giving effect to such exercise. The Shares and Rights were issued in transactions exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and the Shares and Rights were also issued in compliance with Section 3(a)(9) thereunder such that for Rule 144 purposes the holding period for the Shares and Rights and shares of our common stock underlying the Rights may be tacked onto the holding period of the Notes.

On June 4, 2018, pursuant to a Securities Purchase Agreement (Securities Purchase Agreement) between the Company and a non-U.S. person institutional investor (Investor), the Company sold two 8% Senior Secured Convertible Promissory Notes (Notes) for a total face amount of $3,348,765 and a purchase price of $2,270,463 to the Investor in a transaction exempt from registration under Regulation S, as amended promulgated under the Securities Act of 1933.

On July 20, 2018, pursuant to another Securities Purchase Agreement between the Company and a domestic institutional investor, the Company sold two 8% Senior Secured Convertible Promissory Notes for a total face amount of $2,223,525 and a purchase price of $1,507,557 to this institutional investor upon the same terms and conditions as the transaction consummated under the Securities Purchase Agreement in a transaction exempt from registration under Section 4(a)(2) and Regulation D, as amended promulgated under the Securities Act of 1933.

The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act). As of the date of this Prospectus, all of the Rights have been exercised, and neither investor owns more than 4.9% of the issued and outstanding shares of our common stock.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

All schedules have been omitted because the information required to be set forth in the schedules is either not applicable or is shown in the financial statements or notes thereto.

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EXHIBIT INDEX

Exhibit	Description
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended to June 30, 2005 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed June 5, 2006 (Commission File No. 001-16133)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of April 8, 2014 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed April 8, 2014 (Commission File No. 001-16133)
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133)
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.2 to Company s Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133)
3.5	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company s Registration Statement on Form SB-2 (Registration No. 333-39470))
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of June 30, 2017 (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed July 3, 2017 (Commission File No. 001-16133))
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 5, 2017 (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed July 6, 2017 (Commission File No. 001-16133))
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of September 20, 2017 (incorporated by reference to Exhibit 3.1 of the Company s Current Report on Form 8-K filed September 21, 2017 (Commission File No. 001-16133))
3.9	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of May 2, 2018 (Incorporated by reference from Amendment No. 1 to the Company s Registration Statement on Form S-1, filed with the Commission on July 13, 2018)
5.1	Opinion of Wexler, Burkhart, Hirschberg & Unger LLP
10.1	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed June 8, 2018 (Commission File No. 001-16133)
23.1	Consent of Grant Thornton, LLP
23.2	Consent of Wexler, Burkhardt, Hirschberg & Unger (included as part of Exhibit 5.1)
24.1	Powers of Attorney (included on signature page to this Registration Statement)

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Item 17. Undertakings

(1) The undersigned registrant hereby undertakes to provide to the placement agent at the closing specified in the Placement Agency Agreement certificates in such denominations and registered in such names as required by the placement agent to permit prompt delivery to each purchaser.

(2) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(3) The undersigned registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(4) The undersigned registrant hereby undertakes that:

The undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms different from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, Delcath Systems, Inc., a Delaware corporation, has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on August 15, 2018.

DELCATH SYSTEMS, INC.

By: /s/ Jennifer K. Simpson, Ph.D.
Name: Jennifer K. Simpson, Ph.D.
Title: President and Chief Executive Officer

Each person whose signature appears below constitutes and appoints Jennifer K. Simpson and Barbra C. Keck and each of them singly, his or her true and lawful attorneys-in-fact andagents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act and to file the same, with all exhibits thereto and all other documents in connection therewith, with the SEC, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their, his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-1 has been signed by the following persons in the capacities indicated.

SIGNATURE	TITLE	DATE
/s/ Jennifer K. Simpson, Ph.D. Jennifer K. Simpson, Ph.D.	President and Chief Executive Officer and Director (Principal Executive Officer)	August 15, 2018
/s/ Barbra C. Keck, M.B.A. Barbra C. Keck, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 15, 2018
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	Chairman of the Board	August 15, 2018
/s/ William D. Rueckert William D. Rueckert	Director	August 15, 2018
/s/ Marco Taglietti, M.D.	Director	August 15, 2018

Marco Taglietti, M.D.

/s/ Simon Pedder	Director	August 15, 2018
Simon Pedder		