UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the fiscal year ended December 31, 2022

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the transition period from _____ to _____
Commission file number: 001-16133

DELCATH SYSTEMS, INC.

Delaware	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1633 Broadway, Suite 22C New York, NY	**10019**
(Address of principal executive offices)	**(Zip Code)**

212-489-2100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value per share	**DCTH**	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark 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.

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Auditor PCAOB ID Number: 688 Auditor Name: Marcum LLP Auditor Location: New York, NY

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing sale price on the Nasdaq Capital Market of $3.99 per share, as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter was $31,947,845.

At March 24, 2023, the registrant had outstanding 10,061,988 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022.

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Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K for the period ended December 31, 2022 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity, and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2022 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 in Item 1A under "Risk Factors" 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;
- actions by the FDA relating to the Company's New Drug Application resubmission;
- the ability of the Company to respond to FDA queries related to the New Drug Application resubmission;
- the Company's successful inspections by the FDA or foreign regulatory agencies;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and HEPZATO, 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 CHEMOSAT and HEPZATO and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and HEPZATO;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

This Annual Report on Form 10-K and the information incorporated herein by reference may include trademarks, service marks and trade names owned or licensed by us, including CHEMOFUSE, CHEMOSAT, CHEMOSATURATION, DELCATH, HEPZATO, HEPZATO KIT, PHP and THE DELCATH PHP SYSTEM. Solely for convenience and readability, trademarks, service marks and trade names, including logos, artwork and other visual displays, may appear in a non-traditional trademark usage manner, including without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent

under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. All trademarks, service marks and trade names included or incorporated by reference into this Annual Report on Form 10-K are the property of the Company or the Company's licensor, as applicable.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. We will be unable to continue to operate for the foreseeable future without additional capital.
- We will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, complete our clinical trials or conduct future product development and clinical trials.
- Drug development is an inherently uncertain process with a high risk of failure at every stage of development. On February 12, 2013, we received a complete response letter from the FDA declining to approve our New Drug Application, or NDA, in its then current form. We resubmitted a New Drug Application with the FDA on February 14, 2023; however, there is no guarantee that the FDA will accept our resubmitted NDA, or ultimately approve it.
- The Company does not expect to generate significant revenue for the foreseeable future.
- Continuing losses may exhaust our capital resources.
- If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, or conduct future product development and clinical trials.
- 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.
- We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited.
- We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in any other country where we receive marketing authorization or approval.
- The development and approval process in the United States is time consuming, requires substantial resources and may never lead to the approval of HEPZATO by the FDA for use in the United States. The FDA may reject our New Drug Application resubmission or refuse to approve the New Drug Application for HEPZATO.
- If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.
- We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and HEPZATO, and if these third parties do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.
- Purchasers of CHEMOSAT in the EU may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in the EU may not be successful. The success of any of our products may be harmed if the government, private health insurers or other third-party payers do not provide sufficient coverage or reimbursement.

- CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business.
- We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly for us, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and in the EU.
- Changes in health care law and governmental policies and initiatives with respect to health care, including government restrictions on pricing and reimbursement and other health care payor cost-containment initiatives, may have a material adverse effect on us.
- Changes in general market, economic, and political conditions, as well as uncertainty resulting from the COVID-19 pandemic, geopolitical tensions, and other macroeconomic conditions.
- Consolidation in the healthcare industry could lead to demands for price concessions.
- We may not be able to enter into or maintain acceptable arrangements for the supply of components and/or raw materials needed for the manufacture of HEPZATO and/or CHEMOSAT.
- If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize HEPZATO in the United States or complete any future clinical trials.
- If we cannot successfully manufacture CHEMOSAT and HEPZATO, our ability to develop and commercialize the system would be impaired.
- Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing our product in markets outside the EU, because of inadequate infrastructure or an ineffective commercialization strategy.
- Any plan by the Company to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO may not be successful.

Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "Delcath", "Delcath Systems", "we", "our", and "us" refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100 and our internet address is www.delcath.com.

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as the HEPZATO but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver. Approximately consisting primarily of metastatic ocular melanoma, or mOM. Approximately 80% of the estimated 800 patients annually with mOM will be eligible for would be candidates for HEPZATO.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan the treatment of patients with ocular (uveal) melanoma cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

Our clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM, a type of primary liver cancer. Our most advanced development program is the treatment of mOM. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plan to begin the study of HEPZATO to treat such conditions in the near future. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint.

On February 14, 2023, the Company completed a NDA resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO Kit in the treatment of patients with unresectable hepatic-dominant mOM. The resubmission is in response to a September 12, 2013 Complete Response Letter, or CRL, from the FDA for the Company's NDA in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO Kit relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023. We continue to have early access programs in the United States to make HEPZATO available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Cancers in the Liver—A Significant Unmet Need

According to the American Cancer Society's, or ACS*, Cancer Facts & Figures 2023* report, cancer is the second leading cause of death in the United States, with an estimated 609,820 deaths and over 1.9 million new cases expected to be diagnosed in 2023. Cancer is one of the leading causes of death worldwide, accounting for approximately 10 million deaths and 19.3 million new cases in 2020 according to GLOBOCAN, the database of the International Association of Cancer Registries. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the United States in 2018 was $112.5 billion. The liver is often the life-limiting organ for cancer patients and cancer that spreads to the liver is one of the leading causes of cancer death. Cancer that begins in one area of the body often metastasizes to the liver. Patient prognosis is generally poor once cancer has spread to the liver. Consequently, cancers of the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers of the liver consist of primary liver cancer and metastatic liver cancer. Primary liver cancers (hepatocellular carcinoma, or HCC, and Intrahepatic Cholangiocarcinoma 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 cancer, also called liver metastasis, or secondary liver cancer, results from the spread or "metastases" of a primary cancer into the liver. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer. In Europe and the United States, there are over 200,000 primary and metastatic liver tumors per year. It is estimated the total addressable market in the United States for mOM, ICC, HCC breast cancer, neuroendocrine, pancreatic, and colorectal, is over $1.0 billion.

The liver is a difficult organ to treat for certain cancers. Current liver treatment options include surgery, systemic drugs, and minimally invasive or liver directed options. Surgery options include surgical resections, liver transplants, and isolated hepatic perfusion, or IHP. We believe that IHP results in mOM provided rational for PHP in mOM, as well as other tumor types, including colorectal cancer. Systemic options include systemic chemotherapy, immunotherapy agents including KIMMTRAK. Minimally invasive options include external beam radiation therapy and liver directed procedures. Procedures in the liver, liver directed (interventional oncology) are performed by an interventional radiologist. These procedures include trans-arterial chemoembolization (TACE, DEBTACE) and Radioembolization (SIRT, TARE, or Y90). TACE is performing approximately 50,000 to 60,000 treatments per year and Y90 is performing 10,000 to 15,000 treatment per year. We believe that CHEMOSAT and HEPZATO, if approved in the United States, represent an important advancement in regional therapy for liver directed treatment of 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. Patients at our early access programs have included first line of stand alone treatment, first line treatment for those intending to receive KIMMTRAK as second line treatment, and as a third line palliative treatment.

Ocular Melanoma

Ocular melanoma frequently metastasizes to the liver. Based on third party research that we commissioned approximately 5,000-6,200 cases of ocular melanoma are diagnosed in the United States and Europe annually, and approximately 50% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is up to 12 months. There is no one standard of care for patients with ocular melanoma liver metastases. Based on our research, an estimated 800 patients with ocular melanoma liver metastases in the United States, and 1,200 patients in Europe may be eligible for treatment with HEPZATO annually. Currently 55% of the patients have no approved treatment option and most of those patients are treated with multiple lines of therapy. We estimate the annual addressable market for this indication in the United States and Europe is approximately $500 million per year.

Intrahepatic Cholangiocarcinoma

Primary liver cancers include HCC and ICC. According to GLOBOCAN 2020, an estimated 68,500 new cases of primary liver cancer are diagnosed in the United States and Europe annually. According to the ACS, approximately 41,260 new cases of these cancers are expected to be diagnosed in the United States, leading to approximately 30,520 deaths.

ICC is the second most common form of primary liver cancer and according to Wang et al., 2013 J Clin Oncol 31:1188-1195 accounts for 5-30% of primary liver cancers diagnosed in the United States and Europe annually. We believe that 80% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. According to third party research that we commissioned, we estimate that approximately 11,000 ICC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with HEPZATO and CHEMOSAT.

Colorectal Cancer

Colorectal cancer or CRC is one of the most prevalent cancers in the United States and Europe and has a high metastatic rate to the liver. GLOBOCAN 2020 estimates 288,230 colorectal cancer diagnosis per year in the United States and Europe. According to the American Cancer Society, in the United States approximately 151,030 diagnoses leading to 52,580 deaths.

Recent advances in the treatment of primary colorectal cancer have shown encouraging increases in 5-year survival; however, the presence of metastasis is an indicator for increased mortality probability. Approximately 25% of patients will present with liver metastasis at the time of initial primary disease diagnosis. Clark et al., *J Gastrointest Oncol*. 2014;5(5):374-387. We estimate approximately 98,000 CRC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with HEPZATO and CHEMOSAT.

Breast Cancer

Breast cancer or BC is the most diagnosed cancer in women in the United States and worldwide. The American Cancer Society estimates that 287,850 women will be diagnosed with BC in the United States annually. BC is the second leading cancer-related cause of death for women (behind lung cancer) in the United States. GLOBOCAN 2020 estimates are that there are, annually, 726,259 women diagnosed with breast cancer in the United States, Western Europe and the United Kingdom. Recent advances in primary breast cancer treatments have given patients a high 5-year survival rate. The prognosis for patients with breast cancer liver metastasis, however, remains poor.

Approximately 18% of all women diagnosed with breast cancer will also have distant metastatic disease, in which 5% of these patients will have liver only metastasis. Eventually 50% of all metastatic patients will see

their disease progress to the liver in addition to their initial diagnosed metastatic site and in 20% of these patient's liver progression is the cause of mortality. *Deipolyi AR, et al.J Vasc Inter Radiol. 2018;29(9):1226-1235.* Treatment options for patients with multiple sites of metastatic disease vary. We estimate that approximately 6,000 breast cancer patients with hepatic only involvement in the United States and Western Europe (including the United Kingdom and Italy) could be candidates for treatment with HEPZATO and CHEMOSAT. An additional 10,000 patients could receive benefits from HEPZATO and CHEMOSAT in the palliative setting based on local treatment guidelines.

Neuroendocrine Cancer

Neuroendocrine Tumors or NETs or neuroendocrine neoplasia are a rare group of cancers that originate in neuroendocrine cells. NETs can originate anywhere in the body, the most common sites include the digestive tract, rectum, lungs, pancreas, or appendix. The American Society of Clinical Oncology estimates that there are 12,000 new diagnosis of neuroendocrine tumors each year in the United States, and a total of 21,500 in the United States and Europe.

According to *Pape et al. 2008. Endocrine-Related Cancer. 15(4), 1083-1097* NETs have a metastasis rate of between 60-80% and the majority of these accrue in the liver (85%). We estimate that approximately 12,000 NETs patients in the United States, the United Kingdom and the European Union each year could be candidates for treatment with HEPZATO and CHEMOSAT.

Pancreatic Cancer

Pancreatic adenocarcinoma comes with a poor prognosis for those diagnosed with the disease. The American Cancer Society estimates that pancreatic cancer will affect 62,210 patients annually, with 49,830 annual deaths in the United States. Along with GLOBOCAN estimates for Western Europe, pancreatic cancer effects a total of 132,442 patients annually with 105,638 annual deaths.

Upon diagnosis, nearly 75% of patients will have liver metastasis and 58% of those patients will have liver only metastasis. Metastatic pancreatic cancer proves to be a fast-progressing cancer that, once metastasized, leaves the patient with limited treatment options. *Oweira, et al. World J Gastroenterol. 2017;23(10):1872-1880.* We estimate there are approximately 57,600 United States and Western Europe new pancreatic cancer patients each year with hepatic only involvement. Given the rapid progression of the disease it is unknown at this time the estimated number of candidates for treatment with HEPZATO and CHEMOSAT.

About CHEMOSAT and HEPZATO

Our product candidate, the HEPZATO Kit, is a drug/device combination product designed to administer concentrated regional chemotherapy to the liver while controlling systemic exposure and associated side effects. This "whole organ" therapy is performed by isolating the circulatory system of the liver, infusing the liver with a chemotherapeutic agent, and then filtering the blood prior to returning it to the patient's circulatory system. During the procedure, known as percutaneous hepatic perfusion, PHP®, or PHP therapy, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body's circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters adsorb chemotherapeutic agent from the blood, before the filtered blood is returned to the patient's circulatory system thereby reducing systemic exposure to the drug and related toxic side effects.

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 HEPZATO is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. If approved, we expect that the HEPZATO Kit will be appropriate for the

approved indication, regardless of HLA-A *02:01 status. In the United States, melphalan hydrochloride for injection will be included as part of the system, if approved. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Early development of HEPZATO System—FDA Complete Response Letter

Based on clinical trials conducted using an earlier version of our HEPZATO system, in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, seeking FDA approval for use of our HEPZATO system for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver and, subsequently, amended the NDA to include ocular melanoma metastatic to the liver.

In the Spring of 2013, an Oncologic Drug Advisory Committee, or ODAC panel, convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of HEPZATO did not outweigh the risks associated with the procedure. A significant portion of the FDA's presentation to the ODAC panel was focused on the FDA's assessment of treatment-related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension, or low blood pressure, during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression.

In September 2013, the FDA issued a CRL, relating to our NDA. The FDA issues a CRL after the review of an NDA has been completed and questions remain that preclude approval of the NDA in its current form. The deficiencies identified in the CRL included, among other items, the requirement that we conduct an adequate and well-controlled study demonstrating substantial evidence that the effectiveness of the use of this early version HEPZATO system the Company intended to market outweighed its risks. The CRL also required that we address certain clinical, clinical pharmacology, human factors and product quality elements.

In January 2016, we entered into a Special Protocol Assessment agreement, or SPA, with the FDA on the design of a new Phase 3 clinical trial of HEPZATO to treat patients with hepatic dominant ocular melanoma. This SPA represented an agreement with the FDA that a specific Phase 3 trial would adequately address objectives that, if met, would support the submission for regulatory approval of HEPZATO. The SPA's primary endpoint was overall survival, and secondary endpoints included progression-free survival, overall response rate and quality-of-life measures. However, the Company faced significant difficulties, including the fact that the BAC arm was known to have limited efficacy, enrolling patients into the study under the SPA. Therefore, in the summer of 2018, we amended the protocol for the trial to a non-randomized, single-arm study with a different primary endpoint (objective response rate), which terminated the SPA.

Clinical Development Program

The focus of our clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in various disease states to demonstrate efficacy and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT, HEPZATO and the PHP therapy have addressed the adverse event profile and procedure-related risks that led to the issuance of the CRL. Our clinical development program is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory filings and reimbursement in various jurisdictions, including the United States.

The FOCUS Trial

The FOCUS Trial evaluated the safety and efficacy of treatment with the HEPZATO Kit for patients with mOM. The primary endpoint of ORR was assessed by an Independent Review Committee per RECIST v1.1. Per protocol, patients were treated every 6 to 8 weeks for a maximum of 6 cycles. Tumor responses were assessed every 12 weeks (+/- 2 weeks) until disease progression.

Delcath powered the single arm trial to demonstrate a clinically meaningful ORR versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications. Based on this analysis the 95% Confidence Interval for ORR for checkpoint inhibitors was calculated to be 3.6% - 8.3%. The lower bound at the 95% confidence for ORR for HEPZATO Kit needed to exceed 8.3% to demonstrate a clinically meaningful ORR. While this comparator is not an historical control, the FDA did not object to using the meta-analysis of checkpoint inhibitors to provide support for a clinically meaningful ORR.

The FOCUS Trial's intent-to-treat or ITT population was comprised of a total of 102 mOM subjects and the treated population, which the FDA defined as the primary analysis population, was comprised of 91 patients. Of the 91 patients in the treated population, 51 (56.0%) had no prior therapy for liver metastases and 40 (44.0%) had at least one line of prior therapy. An independent Review Committee assessed response status per RECISTv1.1. Treatment with HEPZATO Kit in the treated population resulted in an ORR of 36.3% [95% CI: 26.44, 47.01] including 7.7% of patients with a complete response or CR. The median duration of response was 14.00 months [95% CI: 8.31, 17.74] and the disease control rate or DCR was 73.6% [95% CI: 63.35, 82.31]. The NDA resubmission included updated estimated median overall survival or OS of 20.53 months [95% CI: 16.79, 25.26] and updated estimated OS at 1 year of 0.80 [95% CI: 0.70, 0.87]. Data was cut as of December 2, 2022 and Delcath will continue to follow patients until May 2023 (24 months after the last patient's last treatment). Since the trial started as a randomized trial, supportive analyses comparing against BAC were also conducted.

In the FOCUS Trial safety population (95 patients), 39 patients (41.1%) experienced a treatment-related serious adverse event. The most commonly reported treatment-related serious adverse events were thrombocytopenia, neutropenia and febrile neutropenia which were well-manageable. Five percent of patients experienced treatment-related serious cardiac adverse events; in all cases the events resolved with no ongoing complications. 17 (17.9%) patients withdrew due to an adverse event or a serious adverse event, while 12 (12.6%) received a reduced dose due to an adverse event or serious adverse event. There were no treatment-related deaths in the trial. This is consistent with CHEMOSAT, the HDS device component of the HEPZATO Kit, approved in Europe under a CE mark to deliver melphalan to the liver. The safety data submitted in the NDA is consistent with the CHEMOSAT safety data documented in numerous European single-center and multi-center publications.

CHOPIN Trial

The Leiden University Medical Center completed a Phase 1b trial (CHOPIN trial) on the use of the Delcath CHEMOSAT® Hepatic Delivery System with Melphalan (CHEMOSAT) in combination with the immune checkpoint inhibitors (ICI) ipilimumab and nivolumab to treat patients with metastatic uveal melanoma with liver metastases.

The goal of the CHOPIN trial is to study the safety and potential synergistic effects of systemic ICI therapy ipilimumab plus nivolumab (IPI+NIVO) when combined with Delcath's proprietary liver-targeted percutaneous hepatic perfusion treatment in metastatic uveal melanoma patients. The just released publication presented updated safety and efficacy results from the Phase 1b portion of the trial which were previously presented in June 2022 at the American Society of Clinical Oncology Annual Meeting. The Phase 1b portion of the trial enrolled seven patients each of which were treated with two courses of PHP (melphalan 3mg/kg, max 220 mg per cycle) combined with four courses IPI+NIVO escalating the dosing from 1mg/kg each IPI+NIVO (cohort 1) to IPI 1mg/kg + NIVO 3mg/kg (cohort 2). As previously reported, the Best Overall Response included 1 complete response, 5 partial responses and 1 stable disease accounting for an Objective Response Rate of 85.7% and a Disease Control Rate of 100%. At the cut-off date of November 15, 2022, the median follow-up was 29.1 months (range 8.9 – 30.2), the median PFS was 29.1 months (95% CI 11.9 – 46.3) and the median duration of response was 27.1 months (range 7.4 – 28.5). All patients are still alive and three of four patients who subsequently experienced PD continued with treatment in the form of repeated melphalan PHP (M-PHP) cycles.

The ongoing randomized phase 2 part of the CHOPIN trial comparing M-PHP alone with M-PHP plus IPI/NIVO, which will include another 76 patients (38 per arm), is approximately 50% enrolled and will provide more insight to the efficacy.

The determination of a safe and effective dose was a primary goal of the Phase 1b portion of the CHOPIN trial. Grade 1/2 adverse events were seen in all patients and 71.4% experienced grade 3/4 toxicities. In this phase 1b dose-escalation study combining M-PHP with IPI/NIVO the safe treatment dose was established at IPI 1mg/kg and NIVO 3mg/kg. The authors did observe low-grade immune-related toxicities and PHP-related hematological toxicities in the treated groups. Hematological toxicity is a common adverse event after M-PHP, affecting approximately three-quarters of patients. All 7 patients in the study experienced grade 1/2 anemia. To prevent severe leukopenia/neutropenia, G-CSF was administered within 48 hours after M-PHP in their treatment center. The phase 2 part of the CHOPIN study will provide more information on both hepatic and systemic toxicity associated with the combination therapy.

Market Access and Commercial Clinical Adoption

Europe

Since launching CHEMOSAT in Europe, there has been over 1,343 commercial treatments and CHEMOSAT is currently available in over 23 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.

For the period of December 2018 through February 2022, medac GmbH was the Company's exclusive distributor for CHEMOSAT in Europe and had the exclusive right to market and sell CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland, and the United Kingdom. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe. UK upgraded the status from "Research" to "Special Status".

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 most European countries, the government provides healthcare and controls reimbursement levels. Since the European Union 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. Reimbursement is administered on a regional and national basis. A medical device is typically reimbursed under a Diagnosis Related Groups, or DRG, as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. Currently we have an interim level of reimbursement in Germany. The CE Mark has been affixed to the CHEMOSAT in 23 centers in 4 countries.

On February 28, 2022, CHEMOSAT received Medical Device Regulation certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement.

The release of the clinical study report from the FOCUS Trial will create the opportunity to apply for National Level reimbursement in each European country in regard to metastatic ocular melanoma (mOM). These applications must be made by us on a country-by-country basis, with priority placed on markets where CHEMOSAT is currently used. Currently, CHEMOSAT is approved for reimbursement in Germany. The results from the Focus Trial may also support existing reimbursement mechanisms, such as existing in Germany, allowing more hospital centers to secure funding to utilize CHEMOSAT. This increased level of evidence will ultimately support securing full funding for the treatment under DRG codes.

Reimbursement applications in priority European markets are handled directly by the Company.

Government Regulation

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

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FDCA, and its implementing regulations. HEPZATO is subject to regulation as a combination product, which means it is composed of both a drug product and a device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center within the FDA 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 HEPZATO, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

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

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

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

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate

submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center, and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States' IND are required in the European Union and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

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

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

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a Special Protocol Assessment, or 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.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA must contain extensive chemistry, manufacturing, and control information and be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA should review NDAs within ten months of submission or, if the NDA 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 NDA to an advisory committee for review, evaluation, and recommendation as to whether the NDA should be approved. For new oncology products, the FDA will often solicit an opinion from an Oncology Drug Advisory

Committee, or ODAC, which is 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 the FDA. However, the FDA is not bound by the recommendation of an advisory committee and may deny approval of an NDA by issuing a 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 the applicant or its collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution, or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety and efficacy of approved products which have been commercialized. 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 NDA under Section 505 of the FDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) NDA is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely, in part, upon the FDA's findings of safety and effectiveness for previously approved products. A Section 505(j) NDA, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the U.S. 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 FDA's Office of Orphan Products Development 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 for up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

We have received five orphan drug designations for melphalan in the following indications:

- the treatment of patients with cutaneous melanoma;
- the treatment of patients with ocular melanoma;
- the treatment of patients with neuroendocrine tumors;
- the treatment of patients with primary liver cancer, or HCC; and
- the treatment of cholangiocarcinoma, which includes ICC.

We have received one orphan drug designation for doxorubicin for the treatment of patients with primary liver cancer, or HCC.

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

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors must 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 drug manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could require the drug manufacturer 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 drug 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 Delcath or its present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require the recall of our product from distribution or may 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, any drug modifications, including changes in indications, labeling, or manufacturing processes or facilities, may require a submission to the FDA for its approval of a new or supplemental NDA, which may require the development of additional data or the conduct of 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 that have been tested by the drug manufacturer 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.

Coverage and Reimbursement

Our ability to commercialize any products successfully once approved will depend in part on the availability of coverage and reimbursement from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. Even if we obtain coverage for a given product by a

third-party payor, the third-party payor's reimbursement rates may not be adequate to make the product affordable to patients or profitable to us, or the third-party payors may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining and maintaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. We anticipate obtaining a J-Code for HEPTAZO, once approved. J-Codes are part of the Healthcare Common Procedure Coding System, or HCPCS, code as maintained by CMS. However, there is no guarantee that these billing codes, once granted, or the payment amounts, if any, associated with such codes will not change in the future. Private third-party payors often use CMS as a model for their coverage and reimbursement decisions, but also have their own methods and approval process apart from CMS's determinations. Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. Further, no uniform policy for determining coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Moreover, third-party payors may require patients to obtain prior authorization before certain treatments, such as HEPTAZO, are provided. Therefore, we intend to contract with a third-party hub service to facilitate the pre-authorization process.

U.S. HealthCare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws have been applied to restrict certain business practices in the biopharmaceutical industry in

recent years. These laws include anti-kickback statutes, false claims statutes, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Additionally, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Payments Sunshine Act its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates". HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The majority of states also have statutes or regulations similar to the aforementioned federal fraud and abuse laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities, marketing expenditures, and drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

These federal and state laws may impact, among other things, our proposed sales, marketing and education programs. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, criminal and civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate its business and our results of operations.

Health Reform

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

For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and has had a significant impact on the pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize

price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

European Regulatory Environment

In the European Union, the CHEMOSAT system is subject to regulation as a medical device. The European Union is composed of the 27 Member States of the EU plus Norway, Iceland, and Liechtenstein. Under the EU Medical Device Directive (Directive No 93/42/EEC of 14 June 1993), as last amended, drug delivery products such as the CHEMOSAT system are 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 Device Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the EU market as a single integral unit with melphalan, the product has been governed solely by the EU Medical Device 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.

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

The EU Medical Device 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 Device Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EU to conduct conformity assessments. Under the EU Medical Device Directive, CHEMOSAT has been regulated as a Class IIb medical device and, as such, the Notified Body was 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 comply with the essential requirements of the EU Medical Device Directive and, more recently,

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

A manufacturer without a registered place of business in a Member State of the EU that places a medical device on the market under its own name must designate an authorized representative established in the EU who can act before, and be addressed by a Competent Authority on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Device Directive and, more recently, the EU Medical Device Regulation. The Company's wholly-owned subsidiary, Delcath Systems Ltd. located in Galway, Ireland, serves as the authorized representative of the Company.

The European Commission undertook a review of the EU 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 EU 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 EU Medical Device Regulation, which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution and post marketing evaluation. Due to COVID-related delays experienced by the medical device industry and Notified Bodies alike, on April 17, 2020, the European Parliament adopted the European Commission's proposal to postpone the implementation of the EU Medical Device Regulation or EU 2017/745 by 12 months or until May 26, 2021. Delcath did not achieve EU Medical Device Regulation certification by that date due to COVID-related delays; however, our CE Mark under the EU Medical Device Directive remained effective and allowed us to fully operate in Europe.

On February 28, 2022, CHEMOSAT received medical device certification under the new EU Medical Device Regulation, which replaced CHEMOSAT's prior certification under the EU Medical Device Directive. Achieving EU Medical Device Regulation certification entails a detailed evaluation from a designated EU Notified Body, including an audit of quality systems and a review of documentation supporting safety and performance claims for the device. The EU Medical Device Regulation greatly expands upon existing EU Medical Device Directive requirements, including the level of clinical evidence supporting claims, post-marketing surveillance, database traceability, unique device identification or UDI and increased supply chain oversight. Under the EU Medical Device Regulation, CHEMOSAT's designation has changed from a Class IIb to a Class III medical device.

In the EU, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of the 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, user or other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the EU must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action, or FSCA. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction.

The manufacturer or its authorized representative must notify its customers and/or the end users of the medical device of the FSCA via a Field Safety Notice.

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

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

Failure to comply with the EU Member State laws implementing the Medical Device Directive and, more recently, the EU Medical Device Regulation, the EU and EU Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EU Member State authorities. An enforcement action may result in 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.

Other International Regulations

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

Intellectual Property

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. We hold rights in ten U.S. utility patents, one U.S. design patent, three pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validations of European Patents with claims directed to our filter and frame apparatus in 19 European countries, a European patent with claims directed to our filter apparatus and media in nine countries, and a European patent with claims to a kit of parts, directed to CHEMOSAT®, in 18 countries), five issued foreign counterpart design patents, and two pending foreign counterpart patent applications. Patents directed to our chemotherapy filtration system "Apparatus for Removing Chemotherapy Compounds from Blood" were issued by the United States Patent and Trademark Office in July 2017, October 2018, August 2019, February 2020, and February 2022. The patent issued in August 2019 has claims to a kit of parts capable of being assembled for delivering a small molecule chemotherapeutic agent to a subject. These claims are directed to HEPZATO™ KIT. The patent that issued in February 2020 has claims directed to our methods of treatment. In February 2019, a patent was issued by the United States Patent and Trademark Office with claims directed to a method of using our filter and frame apparatus and in August 2021 a patent was issued with claims directed to our filter and frame apparatus. A Hong Kong patent directed to our Filter and Frame Apparatus was issued in March 2018. A European patent was

granted by the European Patent Office for our chemotherapy filtration apparatus in December 2018 and in July 2019 a European patent was granted by the European Patent Office with claims to a kit of parts, directed to CHEMOSAT®. A European patent directed to a method of using our filter and frame apparatus was granted in April 2019 by the European Patent Office. In August 2019, a European patent was granted by the European Patent Office with claims directed to our filter and frame apparatus and validated in eleven countries to provide additional European patent coverage for our filter and frame apparatus to the European patent directed to the frame apparatus that was granted in April 2017. When appropriate, we actively pursue protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of CHEMOSAT and HEPZATO 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. In March 2022, a European patent was granted by the European Patent Office and validated in eight countries with claims to a kit of parts, directed to CHEMOSAT®.

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

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

In certain circumstances, United States patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. We intend to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted us six orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, we believe that this exclusivity will provide us with added protection once commercialization of an orphan drug designated product begins. There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against us, we may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties and, if licenses are not available, prevent us from manufacturing, selling, or using our product. Additionally, we plan to enforce our intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability, price, and patient's quality of life. We also believe that physician relationships, especially relationships with leaders in the medical, surgical, and oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms

could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of continued economic weakness, which is affecting healthcare budgets and reimbursement.

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

In January 2022, Immunocore Holdings plc announced FDA approval for KIMMTRAK (tebentafusp-tebn) for the treatment of HLA-A *02:01-positive adult patients with unresectable or metastatic uveal melanoma. This is the first drug approved specifically for patients with metastatic uveal melanoma. HLA-A *02:01 patients represent approximately 45% of patients with uveal melanoma. HEPZATO is approved can treat all mOM patients and will be the only drug to treat the remaining 55% of patients. Traditionally, metastatic uveal melanoma patients have been treated with a variety of local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Boston Scientific Corporation, the Covidien Products division of Medtronic plc, Merit Medical Systems, Inc., Varian Medical Systems, Inc., Sirtex Medical Limited, AngioDynamics, Inc., and many others.

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

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar™, GlaxoSmithKline plc), is indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST™, GlaxoSmithKline plc) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb Company) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech, Inc.) may also be included in the competitive landscape for the treatment of metastatic liver disease.

Many of these treatments are approved in Europe and other global markets.

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

Manufacturing and Quality Assurance

We manufacture certain critical medical device components, including our proprietary filter media, and assemble and package CHEMOSAT and HEPZATO at our facility in Queensbury, New York. Our European headquarters and distribution facility in Galway, Ireland conducts final manufacturing, processing, and assembly. We use third parties to manufacture some components of CHEMOSAT and HEPZATO. CHEMOSAT and HEPZATO and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution, and we use third-party vendors to perform the sterilization process.

We are required to comply with the FDA's cGMP regulations and international quality system regulations, including those established by the International Standards Organization (ISO), with respect to products sold in the EU. We are required to maintain ISO 13485 certification for medical devices to be sold in the EU, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. Our facilities are ISO 13485:2016 certified.

Human Capital Management

Our management team is comprised of highly experienced pharmaceutical and biotechnology executives with successful track records in researching, developing, gaining approval for and commercializing novel medicines to treat serious diseases. Each member of our management team has over 10 to 30 years of industry experience Additionally, the team has significant experience in capital raises, mergers/acquisitions, business development, and sales and marketing in the pharmaceutical industry. Our board of directors is constituted by individuals with significant experience in the pharmaceutical and biotechnology industries. As of February 1, 2023, including our management team, we had approximately 52 full time employees, of which 43 are located in the United States and 9 are located in Europe. We intend to hire additional employees as and if funds allow. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe our relationship with our employees is good.

As required, we also engage consultants to provide services to the Company, including quality assurance and corporate services.

We are committed to growing our business over the long-term and increasing value to our stockholders. We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel and to motivate such individuals to perform to the best of their abilities. As a result of the competitive nature of the industry in which we operate, employees have significant career mobility and competition for experienced employees is great. The existence of this competition, and our need for experienced and talented employees to achieve our business objectives, underlies the design and implementation of our compensation programs. At the same time, the Company seeks to keep its approach to compensation simple and streamlined. We provide our employees base salaries and leave and benefits programs that we believe are competitive and consistent with employee positions. In addition, we grant stock options to permanent employees, both upon initial hiring and thereafter, and pay cash bonuses to permanent employees based on the achievement of corporate and/or personal performance objectives.

We have developed corporate policies and guidelines for professional behavior. The Company's policies and practices apply to all employees, regardless of title. These guidelines include our Code of Business Conduct and Ethics, policies for corporate disclosure, insider trading and whistle-blowers.

We value diversity of backgrounds and perspectives in our workforce and we do not discriminate based on race, religion, creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, military and veteran status, sexual orientation or any other protected characteristic as established by federal, state or local laws.

We are committed to the health and safety of our employees, patients and other partners in the healthcare community. We work to promote an environment of awareness and shared responsibility for safety and regulatory compliance throughout our organization, in order to minimize risks of injury, exposure, or business impact.

During the COVID-19 pandemic, we allowed our employees to work remotely where needed and if practicable to ensure the health and safety of our team members. Many of our employees have transitioned back to working on-site, but we continue to provide our employees with the option to work from home.

Available Information

Our website address is www.delcath.com. The information found on, or otherwise accessible through, our website is not incorporated by reference into, and does not form a part of, this Annual Report on Form 10-K or any other report or document we file with or furnish to the SEC. We make available, free of charge, on or through the SEC Filings section of our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We have also posted on our website the Audit Committee Charter, the Compensation and Stock Option Committee Charter, the Nominating and Corporate Governance Committee Charter, the Code of Business Conduct and Ethics and Whistleblower Policy, which govern our directors, officers, and employees.

Item 1A. Risk Factors

An investment in our securities involve a high degree of risk. You should carefully consider the following risks, in conjunction with the financial and other information contained in this Annual Report on Form 10-K. As previously discussed, our actual results could differ materially from our forward-looking statements. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance, financial condition and prospects could be materially and adversely affected and the trading price of our common stock could decline, and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur.

Risks Related to Our Business and Financial Condition

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern as of December 31, 2022. We will be unable to continue to operate for the foreseeable future without additional capital.

Our independent registered public accounting firm issued a report dated March 27, 2023 in connection with the audit of our financial statements as of December 31, 2022, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern including our significant working capital deficiency, significant losses and need to raise additional funds to meet our obligations and sustain our operations. In addition, the notes to our financial statements for the year ended December 31, 2022, included in this Annual Report on Form 10-K, contain a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us in the necessary timeframe, in the amounts we require, on terms that acceptable to us, or at all. If we are unable to raise additional capital our business, prospectus, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. For example, we anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through March 31, 2023, but not beyond. If we are not able to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and/or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

As such, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

We will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we will not be able to further commercialize CHEMOSAT and HEPZATO, complete our clinical trials or conduct future product development and clinical trials.

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.

We will require additional substantial financing to complete our clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize our product in the EU and any other markets where we may receive approval for our products. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through the first quarter of 2023, but not beyond. If we are unable to raise additional capital, our ability to complete product development projects or clinical trials will be impaired. We do not know if additional financing will be available on commercially reasonable terms or at all. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC), took control and was appointed receiver of Silicon Valley Bank ("SVB"). If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

If we are unable to obtain additional financing in the near-term , we will not be able to further commercialize CHEMOSAT and HEPZATO, obtain regulatory approvals or complete our development projects or clinical trials, which would result in a complete loss of an investment in our securities.

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

- clinical studies, including closing our Phase 3 clinical trial in ocular melanoma liver metastases;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- executive compensation, including the cost of attracting senior executives;
- 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 capital 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. If we are not able to raise additional capital in the near term, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and/or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment.

We will need additional capital to maintain our operations. If we cannot raise additional capital before March 31, 2023, we may be unable to comply with the terms and conditions of our Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue"). If we breach the Avenue Loan Agreement, this may have adversely impact our business and financial condition.

On August 6, 2021, we entered into the Avenue Loan Agreement with Avenue, pursuant to which, we have borrowed $15 million as of the date hereof. Pursuant to the Avenue Loan Agreement, we made monthly interest-only payments during the first fifteen months of the term of the Avenue Loan Agreement and began principal payments in December 2022. We are now required to make equal monthly payments of principal, plus accrued

interest, until the Avenue Loan Agreement's maturity date. If we prepay the Avenue Loan Agreement, we will be required to pay prepayment fee of 1%. On the maturity date or on the date of the prepayment of the borrowed amount under the Avenue Loan Agreement, we must also make an incremental final payment equal to 4.25% of the aggregate funding. On March 15, 2023, the Company returned to Avenue the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance.

The Avenue Loan Agreement bears interest at an annual rate equal to the greater of (a) the sum of 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at December 31, 2022 was 15.2%. The Avenue Loan Agreement is secured by all of the Company's assets globally, including intellectual property. The amount borrowed pursuant to the Avenue Loan Agreement matures on August 1, 2024.

The Avenue Loan Agreement contains customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Avenue Loan Agreement and the occurrence of a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, the failure to deliver an unqualified audit report and board approved financial projections within time periods set forth in the Avenue Loan Agreement, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. In the event of default by us under the Avenue Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Avenue Loan Agreement, which could harm our business, operations and financial condition.

We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through March 31, 2023, but not beyond, and as a result, if we do not make our required monthly repayment on April 1, 2023, we would be in default the Avenue Loan Agreement. If we were to be in default of the Avenue Loan Agreement, our business and financial condition may be adversely impacted and result in us losing rights to certain or our assets, including intellectual property that is secured by the Avenue Loan Agreement. Furthermore, if we default on any installment under the Avenue Loan Agreement, we will not be eligible to use Form S-3 registration statements for an extended period of time, which could further adversely impact our ability to raise additional financing.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We received a complete response letter from the FDA declining to approve our NDA in its then current form. There can be no assurance that our recent resubmission will be accepted by FDA or will not result in another Complete Response Letter.

Preclinical testing and clinical trials are long, expensive, and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky, and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability, or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

In response to our NDA, which we submitted to the FDA in August 2012 seeking approval for use of our HEPZATO for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its then current form and issued a complete response letter, or CRL. A CRL is issued by the FDA when the review of an NDA is completed, and deficiencies remain that preclude approval of the NDA in its current form. The deficiencies in the CRL included, but were not limited to, a statement that we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of HEPZATO using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of HEPZATO outweigh its risks." The FDA also required that the additional clinical trial(s) be conducted using the product we intend to market. Prior to conducting additional clinical trials, we were required to satisfy certain

other requirements of the CRL, including, but not limited to, product quality testing, pre-clinical studies and human factors validation information.

We have completed a pivotal Phase 3 trial in ocular melanoma metastases. We will need to justify how the results of the study support a favorable risk-benefit assessment, particularly whether the response rate is sufficient to overcome the toxicity of HEPZATO. FDA may review and issue another CRL if it does not conclude that the clinical benefits outweigh the risks and that HEPZATO is safe and effective for use in the intended population.

In addition, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for HEPZATO with other drug therapies. In 2014, we initiated a Phase 2 clinical trial with HEPZATO for hepatocellular carcinoma, or HCC, in both the United States and Europe. In 2015, the Phase 2 clinical trial for HCC was expanded to include a cohort of patients with intrahepatic cholangiocarcinoma, a type of primary liver cancer, or ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market's perception of these clinical data or FDA's perception of this clinical data, may adversely impact our ability to obtain approval, and our financial condition. We have ***paused*** our work on this trial while we reevaluated the trial design. Additionally, even if the results of our Phase 2 clinical trial for HCC 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.

Raising additional capital may cause dilution to our existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require it to relinquish proprietary rights.

Significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds and we anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through the first quarter of 2023, but not beyond. To the extent that we raise additional capital by issuing equity securities, existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. In addition, the exercise of outstanding warrants and options will also cause dilution. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming its stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market.

Continuing losses may exhaust our capital resources.

As of December 31, 2022, we had $11.8 million in cash and cash equivalents. We have had minimal revenue to date, and have a substantial accumulated deficit, recurring operating losses and negative cash flow. We are not profitable and have incurred losses in each year since commencing operations. For the years ended December 31, 2022 and 2021, we incurred net losses of approximately $36.5 million and $25.6 million, respectively and expect

to continue to incur losses in 2023. To date, we have funded operations through a combination of private placements and public offerings of our securities, debt financing including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, engage in product development and the regulatory approval process and commercialization of CHEMOSAT and HEPZATO or any other versions of these products. If we are unable to raise capital or generate sufficient revenue, we may not be able to pay our debts when they become due and may have to seek protection under federal bankruptcy law or enter into a receivership.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. Our ability to generate any product revenue from our current or future product candidates also depends on a number of additional factors, including our ability:

- successfully complete research and clinical development of current and future product candidates and obtain regulatory approval for those product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate, scaled up and legally compliant manufacturing of bulk drug substances and drug products to maintain sufficient supply;
- launch and commercialize any product candidates for which marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability. Even if we successfully complete development and regulatory processes for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease our operations.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition.

We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business (other than intellectual property infringement actions) that could negatively affect our business operations and financial condition, including securities class actions and shareholder derivative actions, both of which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. For information on past legal proceedings, please see "Item 3. Legal

Proceedings." Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both. Additionally, we may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate coverage amounts and may incur significant increases in insurance costs.

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

Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT and HEPZATO and we have only developed these products for the treatment of cancers in the liver. If CHEMOSAT and HEPZATO for the treatment of cancers in the liver fail as commercial products, we have no other products to sell. In addition, since CHEMOSAT currently is approved for commercialization solely in the European Union, or the EU, and limited other jurisdictions (including the United Kingdom), if we are unsuccessful in commercializing the product in the EU and/or if HEPZATO is not approved in the United States and elsewhere, we will have no means of generating revenue. Accordingly, we may not generate material revenues from product sales in the United States in the next year, if at all. As a result, our revenue sources are, and will remain, extremely limited unless and until our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and HEPZATO may not be approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in economic growth, supply chain shortages and disruptions, increases in inflation rates, higher interest rates and uncertainty about economic stability.

The COVID-19 pandemic has had, and may continue to have, an impact on various aspects of our business and that of third parties on which we rely. There remains a high level of uncertainty due to the potential spread of new variants and surges in COVID-19 cases, and this could continue to harm and/or delay our research, development and commercialization efforts, increase our costs and have a material effect on our operations, including by impacting regulatory authorities' ability to review and/or inspect required facilities or submissions. In addition, the COVID-19 pandemic has impacted the global supply chain making it more difficult and/or impossible for us to obtain a sufficient supply of critical materials for our operations.

The COVID-19 pandemic has affected many countries, including the United States and several European countries, where we conducted our FOCUS Trial. In response to the pandemic, hospitals participating in the trials in affected countries took a number of actions, including restricting elective and other procedures that were not deemed to be life-threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials had the start of their treatments postponed and ongoing treatment regimens were delayed. In addition, we did not have sufficient access to monitor trial data on a timely basis. These restrictions had a materially adverse effect on our clinical operations.

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

The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, or do not improve, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

Further downgrades of the U.S. credit rating, automatic spending cuts, or a government shutdown could negatively impact our liquidity, financial condition and earnings.

U.S. debt ceiling and budget deficit concerns have increased the possibility of credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Moreover, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our ability to access the debt markets on favorable terms. In addition, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to FDA and Foreign Regulatory Approvals and Regulatory Matters

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

We cannot sell or market HEPZATO with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of a NDA for HEPZATO. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agents or compounds used in our system. We are seeking approval of HEPZATO for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. We must obtain separate regulatory approvals for HEPZATO with melphalan, and every other chemotherapeutic agent or other compound used with the system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of HEPZATO with melphalan or any other chemotherapeutic agent or compound we use in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for HEPZATO and the use of

melphalan or other chemotherapeutic agents, our business, results of operations, financial condition and prospects would be materially and adversely affected.

In August 2012, we submitted an NDA seeking an indication for ocular melanoma liver metastases for HEPZATO. In September 2013, the FDA issued a complete response letter or CRL indicating that we must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of HEPZATO using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of HEPZATO outweigh its risks. Our Phase 3 trial in ocular melanoma liver metastases, the FOCUS Trial, was not randomized and used a different primary efficacy outcome measure. Failure to obtain FDA approval for HEPZATO will have a material adverse effect on our business, financial condition, and results of operations and prospects.

On February 14, 2023, the Company completed a NDA resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023.

The resubmission is in response to the September 12, 2013 CRL from the FDA. The NDA resubmission contains comprehensive data and information relating to the matters identified in the CRL. FDA may find our attempt to address the issues in the 2013 CRL insufficient to support approval and we may receive another CRL, which would have significant adverse effects on our business operations.

Even if we obtain regulatory approval for HEPZATO in the United States, our ability to market HEPZATO 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 a NDA for HEPZATO, our ability to market and promote HEPZATO would be limited to the approved indication, so even with FDA approval, HEPZATO may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market HEPZATO, if approved by the FDA, for its approved indication and could be subject to enforcement action for off-label marketing. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, FDA warning letters, corrective advertising and potential civil and criminal penalties.

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

The clinical trial data on our product was limited to specific types of liver cancer. In 2010, we concluded a Phase 3 clinical trial of HEPZATO with a prior version of the medical device and procedure in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of that same version of HEPZATO in patients with primary and metastatic melanoma stratified into four arms.

We have completed the dosing phase and analysis of the primary endpoint of an open-label Phase 3 clinical trial in ocular melanoma liver metastases called the FOCUS Trial.

It may take several years if the FDA or foreign regulatory authorities requests additional clinical trials of HEPZATO relating to our NDA submission, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system, or the period required for review of any application for regulatory agency approval;
- enrollment in any additional clinical trials may proceed more slowly than expected;
- any other clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

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

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

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

We are limited to marketing CHEMOSAT in the EU as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of

administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EU where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from CHEMOSAT and/or to prescribe the use of melphalan independently, our sales opportunities in the EU will be significantly limited.

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

In April 2012, we obtained the required certification from a designated EU Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Device Directive and affix the CE Mark to the Generation Two version of CHEMOSAT. More recently, on February 28, 2022, we obtained Medical Device Regulation certification under the new European Medical Devices Regulation [2017/745/EU]. In order to maintain the right to affix the CE Mark in the EU, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by the European Notified Body, and the right to affix the CE Mark to the Generation Two version of CHEMOSAT may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that HEPZATO is approved by the FDA or CHEMOSAT by any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any pre-clinical or clinical trials that we conduct post-approval. In addition, post-marketing requirements for HEPZATO may include implementation of a risk evaluation and mitigation strategies, or REMS, program to ensure that the benefits of the product outweigh its risks. A typical REMS may include a medication guide, a patient package insert, a communication plan to healthcare professionals, restrictions on distribution or use and/or other elements to assure safe use of the product. However, our discussions with the FDA have indicated that a medication guide or communication plan will not be required.

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 NDAs or supplements to approved NDAs;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved NDAs;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, FDA warning letters or untitled letters, or holds on clinical trials;

- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

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

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

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

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

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

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

We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and HEPZATO, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for our products, but rely on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We rely on third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with

our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for HEPZATO if these requirements are not met.

Purchasers of CHEMOSAT in Europe may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in Europe may not be successful.

We have obtained the right to affix the CE Mark for CHEMOSAT, and we intend to seek third-party or government reimbursement within those countries in the Europe where we expect to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic-related group code, or ZE Code, which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. There are also no assurances that third-party payors or government health agencies in Europe will reimburse use of CHEMOSAT in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in another European country. 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 Europe.

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

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

Further implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT and HEPZATO and the demand for CHEMOSAT and HEPZATO.

Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies.

CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business.

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

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

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to certain payments and other transfers of value provided to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; and
- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including

commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

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

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

For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes

for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

Risks Related to Manufacturing, Commercialization and Market Acceptance of CHEMOSAT and HEPZATO

Manufacturers of melphalan may be unable to provide adequate supplies of melphalan.

Under the current regulatory scheme in the European Union, 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 European Union for over a decade, we are aware that there are currently three approved manufacturers of melphalan in certain countries of the European Union. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the European Union. Additionally, melphalan is not available in certain foreign countries outside the European Union where we may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, we will be unable to commercialize CHEMOSAT in these markets, thereby limiting future sales opportunities.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents, we will be unable to successfully commercialize HEPZATO in the United States or complete any future clinical trials.

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

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

We manufacture certain components of our products, including our proprietary filter media, and assemble and package CHEMOSAT and HEPZATO at our facility in Queensbury, New York. We have established our European headquarters in Galway, Ireland and conduct finishing operations, assembly, packaging, labeling and distribution at this facility. We currently utilize third parties to manufacture some components of CHEMOSAT and HEPZATO. We may have difficulty obtaining components for our products from our third-party suppliers in a timely manner or at all, which may adversely affect our ability to deliver CHEMOSAT and HEPZATO to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT and HEPZATO may adversely affect our ability to obtain regulatory approval in the United States and other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture CHEMOSAT and HEPZATO in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

We have implemented quality systems throughout our organization designed to enable us to satisfy the various international quality system regulations, including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization, or ISO, with respect to products sold in the European Union. We are required to maintain ISO 13485 certification for medical devices to be sold in the European Union, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. All of our facilities are presently ISO 13485:2016 certified. If our Queensbury, New York facility fails to maintain compliance with ISO 13485 and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble CHEMOSAT and HEPZATO in our Galway, Ireland facility or elsewhere in the European Union, and any facilities in the European Union would have to obtain and maintain similar approvals or certifications of compliance.

Although Delcath is not aware of any direct impacts of the war between the Ukraine and the Russian Federation on its supply chain, the war could adversely impact our ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its third-party suppliers in a timely manner or at all. In addition, at this time, although the Company is not aware of any direct impacts, any increase in COVID cases and associated restrictions could adversely impact the Company's ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its third-party suppliers in a timely manner or at all. A rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company's ability to meet anticipated timelines.

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

While we have written contracts and supply agreements for key components for CHEMOSAT and HEPZATO, we do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and HEPZATO. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture CHEMOSAT and HEPZATO in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and HEPZATO in the United States, the European Union and elsewhere may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT and HEPZATO are currently manufactured for us in small quantities. We may require significantly greater quantities to further commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and HEPZATO may be delayed.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT and HEPZATO in markets outside the European Union, because of inadequate infrastructure or an ineffective commercialization strategy.

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

We may not be successful in our efforts to expand the commercialization of CHEMOSAT in the European Union, and we may not be successful in commercializing HEPZATO in the United States and CHEMOSAT or HEPZATO in other foreign countries. Each country requires a different commercialization strategy, so our European Union marketing strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market CHEMOSAT and HEPZATO in each of our target markets may fail in any or all of those markets.

We may use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO may not be successful.

We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in the search for alliances. As a result, we may not be able to enter into alliances on acceptable terms, if at all. Our collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and HEPZATO or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations, or our collaborators may breach their agreements with us. In addition, any third parties with whom we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We will not control the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and HEPZATO or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

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

Currently we have only received authorization to market CHEMOSAT in the European Union and intend to seek similar authorization or approvals in other foreign countries. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

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

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

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

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

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

Risks Related to our 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 products. 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 employment, manufacturing, consulting and other third-party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

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

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

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

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

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

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

Our success depends in part on our ability to commercialize CHEMOSAT and HEPZATO prior to the expiration of our patent protection.

Our patent protection for CHEMOSAT and HEPZATO is primarily in the United States and the EU. We currently have patents in the United States and the EU directed to our product, system, components, procedure, and method of treatment, with additional design patent protection in Argentina, Canada, Europe, the UK, and Japan. Our patents provide patent protection for our CHEMOSAT hepatic delivery system, HEPZATO,

hemofiltration cartridge apparatus, hemofiltration cartridge design, methods of treatment of a subject with cancer in accordance with various embodiments of our system, embodiments of our system for delivering a high concentration of a small molecule chemotherapeutic agent to a subject while minimizing systemic exposure to the small molecule chemotherapeutic agent, and methods of setting up a filter apparatus for hemofiltration in accordance with our procedures using our proprietary hepatic deliver system. However, patents have a limited lifespan. In the United States and the EU, the ordinary statutory natural expiration of a utility patent is generally 20 years from its filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

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

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

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

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

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, there may be some uncertainties associated with avoiding patent infringement. 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;
- we may become prohibited 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 third-party 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 covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

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

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

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

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign

courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

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

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

We may rely primarily on trade secret protection for important proprietary technologies.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us in countries where we do not have patent protection.

Similar considerations apply in foreign countries where we receive approval and do not have issued patents for the current version of CHEMOSAT and HEPZATO. In these countries, our ability to successfully commercialize CHEMOSAT and HEPZATO will depend on our ability to maintain trade secret protection in these markets.

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

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

Risks Related to Our Common Stock

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

The trading price of our common stock has been, and we expect it to continue to be, volatile. For example, the trading price of our common stock has varied between a high of $7.95 on January 3, 2022 and a low of $2.34 on October 13, 2022. The price at which our common stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital needed and the terms on which it may be raised, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of our common stock to fluctuate are the risks described elsewhere in this "Risk Factors" section and other factors, including:

- fluctuations in our quarterly operating results or the operating results of competitors;
- variance in financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;
- conditions and trends in the markets served;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of competitors;
- changes in pricing policies or the pricing policies of competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

- potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC;
- the commencement or outcome of litigation involving us, our general industry or both;
- our filing for protection under federal bankruptcy laws;
- changes in capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of common stock by stockholders; and
- the trading volume of our common stock.

In addition, the stock markets and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of 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 the Company 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.

Because of volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business.

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

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

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

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

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

Certain provisions of our Amended and Restated Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of

stockholders might favor a change in management. These provisions include providing for a staggered board of directors and authorizing the board of directors to fill vacant directorships or increase the size of the board of directors.

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

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

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

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

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

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

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. Securities and industry analysts do not

currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our shares of Common Stock adversely, or provide more favorable relative recommendations about our competitors, the price of our shares of Common Stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

We have identified material weaknesses in our internal control over financial reporting. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Management determined there was material weaknesses that existed at December 31, 2022. The material weaknesses relate to detection and application of the Company's expense policy on its share-based compensation under the accelerated method. We have commenced measures to remediate this material weaknesses and will design additional key controls in order to ensure the Company's share-based compensation is calculated under the accelerated method. We will continue to assess our finance and accounting staffing needs to ensure remediation of this material weakness. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. If not remediated, this material weakness could result in further material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filing of required periodic reports. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of the stock could be adversely affected, and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Management will be required to assess the effectiveness of our internal controls annually. However, for as long as we are a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

General Risk Factors

The loss of key personnel could adversely affect our business.

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

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

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

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

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

We will continue to incur significant costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations have increased, and will continue to increase, our legal and financial compliance costs and make some activities more time- consuming and costly. The increased costs may increase our net loss. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage as we did prior to becoming a public company. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our board committees or as our executive officers.

We are a "smaller reporting company" and have elected to comply with reduced public company reporting requirements, which could make our Common Stock less attractive to investors.

Because our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting Common Stock held by non-affiliates was less than $560.0 million measured on the last business day of our second fiscal quarter, we qualify again as a "smaller reporting company" as defined in the Exchange Act. Accordingly, we may provide less public disclosure than larger public companies, including, the inclusion of only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure. We are also no longer required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our Common Stock less attractive as a result of our reliance on these exemptions. If some investors find our Common Stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our Common Stock and the market price for our Common Stock may be more volatile.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate offices currently occupy 6,877 square feet of office space at 1633 Broadway, Suite 22C, New York, New York under a sub-lease agreement that expires in May 2023. We also own two buildings comprised of approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, New York and 6,000 square feet at 95-97 Park Road in Queensbury, New York. These facilities house manufacturing, quality assurance and quality control, research and development, and office space functions. We also own approximately four acres of land at 12 and 14 Park Road in Queensbury, New York. In addition, we sub-lease a facility for office and manufacturing comprised of approximately 2,409 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires in August 2026. We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet current operational needs.

Item 3. Legal Proceedings.

medac GmbH

In April 2021, the Company's wholly-owned subsidiary, Delcath Systems Ltd, issued to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), an invoice for a €1 million milestone payment under a License, Supply and Marketing Agreement dated December 10, 2018 (the "medac Agreement") between medac and the Company. The medac Agreement provided to medac the exclusive right to market and sell CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland and the United Kingdom for which the Company was entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

In response to medac's subsequent dispute and non-payment of the invoice, on October 12, 2021, the Company notified medac in writing that it was terminating the medac Agreement due to medac's nonpayment of the €1 million milestone payment, with the effective date of termination of the medac Agreement being April 12, 2022. medac disputed having an obligation to make the milestone payment and demanded withdrawal of the termination notice. In response to medac's continued failure to make the milestone payment and its demand for the Company to withdraw its termination notice, on December 16, 2021, we initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement. Thereafter, on December 30, 2021, we received a letter from medac stating that, due to our failure to withdraw the termination notice, medac was terminating the medac Agreement with immediate effect. In a separate letter, medac agreed to orderly transition through February 28, 2022 in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately $0.2 million. As a result of the early termination of the medac Agreement, the Company revised its estimate of the contract life which resulted in an acceleration of $1.742 million of revenue recognition associated with deferred revenue.

On December 30, 2022, the parties reached a final settlement of the matter and Delcath has agreed pay medac a royalty on sales of CHEMOSAT units over a defined minimum for a period of five years or until a maximum payment has been reached. The settlement terms also contain a minimum annual payment of $0.2 million in the event the annual royalty payment does not reach the agreed on minimum payment amount. The Company has estimated the settlement to be $1.2 million and recorded $1.0 million it as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet and a $1.2 million charge in selling, general and administrative expenses in the Company's condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2022.

Lachman Consultant Services, Inc.

On January 24, 2023, Lachman Consultant Services, Inc ("Lachman") served the Company with a Complaint alleging that Delcath owes Lachman approximately $0.9 million in unpaid consulting fees plus interest, costs and

attorneys' fees. The lawsuit is Lachman Consultant Services, Inc. v. Delcath Systems, Inc., Index No. 650103-2023 (New York Supreme Court, New York County. The Company filed an answer to Lachman's Complaint on February 22, 2023. On March 17, 2023, Delcath responded to Lachman's March 3, 2023 Motion for Partial Summary Judgment. On March 20, 2023, the Court denied Lachman's request that the case be moved into the Commercial Division. The current return date of Lachman's motion for partial summary judgment is March 31, 2023. The dispute arises from a July 22, 2021 agreement between Lachman and Delcath under which Lachman was to provide assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. In August 2022, the Company disputed $0.3 million of charges from Lachman. As of December 31, 2022, the Company has accrued $0.9 million as accrued liability on the Company's condensed consolidated balance sheet. The Company plans to vigorously defend this lawsuit and has reserved its rights to dispute all of Lachman charges as the litigation proceeds.

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties, or injunctions prohibiting us from selling our products or engaging in other activities. The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods.

Item 4. Mine Safety Disclosures.

Not applicable.

Part II

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

Market Information. The Company's common stock, par value $0.01 per share, is traded on the Nasdaq Capital Market under the symbol "DCTH".

Holders. On March 16, 2023, there were approximately 64 holders of record of our common stock based on information furnished by American Stock Transfer and Trust Company, LLC, the transfer agent for our securities.

Dividend Policy. The Company has never declared or paid cash dividends on its common stock and has no intention to do so in the foreseeable future.

Recent Sales of Unregistered Securities.

On July 18, 2022, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company agreed to sell and issue to the investors in a private placement (i) an aggregate of 690,954 shares of the Company's common stock at a purchase price of $3.98 per share and (ii) 566,751 pre-funded warrants to purchase common stock at a purchase price of $3.97 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. Upon the closing of the private placement on July 20, 2022, the Company received gross proceeds of approximately $5.0 million, before the deduction of offering expenses payable by the Company. The Company intends to use the net proceeds of the private placement for working capital and other general corporate purposes. Based in part upon the representations of the investors in the securities purchase agreement, the offering and sale of the securities was made in reliance on the exemption afforded by Regulation D under the Securities Act of 1933, as amended (the "Securities Act"), and corresponding provisions of state securities or "blue sky" laws. The sale of the securities did not involve a public offering and was made without general solicitation or general advertising. The investors represented that they are accredited investors, as such term is defined in Rule 501(a) of Regulation D under the Securities Act, and that they were acquiring the securities for investment purposes only and not with a view to any resale, distribution or other disposition of the securities in violation of the U.S. federal securities laws.

On December 7, 2022, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company agreed to sell and issue to the investors in a private placement (i) an aggregate of 1,448,889 shares of the Company's common stock at a purchase price of $2.90 per share, and (ii) 692,042 pre-funded warrants to purchase common stock at a purchase price of $2.89 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. Upon the closing of the private placement on December 13, 2022, the Company received gross proceeds of approximately $6.2 million, before the deduction of offering expenses payable by the Company. The Company intends to use the net proceeds of the private placement for working capital and other general corporate purposes. Based in part upon the representations of the investors in the securities purchase agreement, the offering and sale of the securities was made in reliance on the exemption afforded by Regulation D under the Securities Act and/or Regulation S under the Securities Act inasmuch as certain investors are not a "U.S. person" (as defined in Rule 902 under the Securities Act) and the requirements of Rule 903 under the Securities Act are otherwise met, and corresponding provisions of state securities or "blue sky" laws. The sale of the securities did not involve a public offering and was made without general solicitation or general advertising. The investors represented that they are accredited investors, as such term is defined in Rule 501(a) of Regulation D under the Securities Act, and that they were acquiring the securities for investment purposes only and not with a view to any resale, distribution or other disposition of the securities in violation of the U.S. federal securities laws.

Repurchases of Equity Securities. The Company did not repurchase any shares of our common stock during the fourth quarter of the fiscal year ended December 31, 2022.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2022 with respect to compensation plans (including individual compensation arrangements) under which shares of common stock of the Company are authorized for issuance.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,604,053	$ 9.67	870,508
Equity compensation plans not approved by security holders [1]	630,999	$11.89	0
Total	2,235,052	$10.30	870,508

(1) Includes (a) stock options for an aggregate of 499 shares of Common Stock issued under the Company's 2019 Equity Incentive Plan, which allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards to the Company's officers, directors, employees, consultants, and advisors, including options to purchase shares of common stock at exercise prices not less than 100% of fair value on the dates of grant. As of November 2, 2020, no additional grants may be made under this plan, which has been superseded by the Company's 2020 Omnibus Equity Incentive Plan; however, outstanding awards granted under this plan will remain outstanding and continue to be administered in accordance with the terms of this plan and the applicable award agreements;(b) pursuant to an employment agreement dated as of August 31, 2020 between the Company and Gerard Michel, the Company's Chief Executive Officer, on October 1, 2020, a nonqualified and non-plan stock option "inducement award" to purchase 498,000 shares of the Company's common stock in reliance on Nasdaq Rule 5635(c)(4) pursuant to the terms of a stock option award agreement between the Company and Mr. Michel. Additional information about this stock option award will be included in the Company's proxy statement for its 2023 annual meeting of stockholders under the heading "Gerard Michel Employment Agreement";(c) new hire inducement awards to purchase 132,500 shares of the Company's common stock in reliance on Nasdaq Rule 5635(c)(4) pursuant to the terms of a stock option award agreement between the Company and five employees hired during 2022.

Item 6. [Reserved.]

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

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

Our clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM, a type of primary liver cancer. Our most advanced development program is the treatment of ocular melanoma liver metastases, or mOM. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plan to begin the study of HEPZATO to treat such conditions in the near future. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint. For information on the FOCUS Trial, see "Part I, Item 1. Business—Clinical Development Program—The FOCUS Trial".

On February 14, 2023 we filed a New Drug Application resubmission to the US Food and Drug Administration (the FDA) for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO Kit in the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma, or mOM. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023.

The resubmission is in response to a September 12, 2013 Complete Response Letter, or CRL, from the FDA for the Company's NDA in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO Kit relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023. We continue to promote our early access programs in the United States to make HEPZATO readily available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States. There are currently patients enrolled in our early access program sites.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Liquidity and Capital Resources

At December 31, 2022, we had cash, cash equivalents and restricted cash totaling $11.8 million, as compared to cash, cash equivalents and restricted cash totaling $27.0 million at December 31, 2021. During the years ended December 31, 2022 and 2021, the Company used $25.0 million and $22.6 million respectively, of cash in our operating activities.

On March 10, 2023, we had a banking relationship with SVB. As of the closure of SVB on March 10, 2023, we held approximately $1.1 million of unrestricted cash in deposits held in SVB, $4.0 million held in a restricted SVB account as required per the Avenue Loan Agreement and approximately $0.2 million of restricted cash held in SVB collateral accounts as required per our line of credit for the property in New York City and our credit card program with SVB. SVB was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors will have access to all of their money starting March 13, 2023. On March 13, 2023, we were able to access all of our cash, cash equivalents and investments held at or through SVB. While we have not experienced any losses in such accounts, the recent failure of SVB exposed us to significant credit risk prior to the completion by the FDIC of the resolution of SVB in a manner that fully protected all depositors. We are evaluating alternative solutions which management believes does not expose us to significant credit risk or jeopardizes our liquidity.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve consistent profitability. We have historically funded our operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of our common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements. We have entered into a Controlled Equity Offering SM Sales Agreement (“ATM Sales Agreement”), with Cantor Fitzgerald & Co. (the “Sales Agent”), pursuant to which we may offer and sell, at our sole discretion through the Sales Agent, shares of our common stock having an aggregate offering price of up to $17.0 million. To date, we have sold approximately $4.0 million of our common stock, prior to issuance costs, under the ATM Sales Agreement. We will need to raise additional capital under structures available to us, including debt and/or equity offerings.

These circumstances raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities, or through partnering or licensing transactions in which we receive cash to support our future operations. If we are unable to secure additional capital or if additional capital is not available on favorable terms for us, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

Our capital commitments over the next twelve months include (a) $6.9 million to satisfy December 31, 2022 accounts payable, accrued expenses and lease liabilities and (b) $8.6 million of loan principal payments. Our capital commitments past the next twelve months include (a) $0.2 million of lease liabilities; (b) $1.0 million for settlement of litigation with medac; (c) $3.4 million of loan principal payments; and (d) $5.0 million of convertible note principal payments, if the holders do not elect to convert the notes into equity. On March 15, 2023, the Company returned to Avenue the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance.

We also expect to use cash and cash equivalents to fund our potential approval of HEPZATO from the FDA, commercialization of HEPZATO and CHEMOSAT and any future clinical research trials and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining regulatory approvals and complying with applicable laws and 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.

On August 6, 2021, the Company entered into the Avenue Loan Agreement with Avenue for a term loan in an aggregate principal amount of up to $20 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at December 31, 2022 was 15.2%. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. Additional information regarding the Avenue Loan can be found in Note 10 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K. On March 15, 2023, the Company returned to Avenue the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance.

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock and 566,751 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $3.98 and the pre-funded warrants were sold at a price of $3.97 per pre-funded warrants. pre-funded warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $5.0 million before deducting offering expenses.

On December 13, 2022, the Company closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $2.90 and the pre-funded warrants were sold at a price of $2.89 per pre-funded warrants. The pre-funded warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $6.2 million before deducting offering expenses.

Additionally, while the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased recently to levels not seen in decades. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Recent bank failures may also have an impact on our liquidity and capital resources. For example, on March 10, 2023, the FDIC, took control and was appointed receiver of SVB. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy. See "Risk Factors" for additional risks associated with our substantial capital requirements.

Comparison of Results of the Years Ended December 31, 2022 and 2021

Revenue

We recorded approximately $2.5 million in product revenue and $0.2 million in other revenue during the year ended December 31, 2022. During the same period in 2021, we recorded $1.3 million in product revenue and $2.3 million in other revenue. Our product revenues increased $1.2 million primarily due to transitioning to direct selling of CHEMOSAT beginning in March 2022. Other revenues decreased as a result of the amortization of our license agreement with medac, pursuant to which medac had served as our exclusive distributor of CHEMOSAT in the United Kingdom and European Union. On December 30, 2021, medac terminated the license agreement and ceased distribution activities at the end of a mutually agreed transition period on February 28, 2022. As a result of the termination of the license agreement, the Company changed its estimate of the contract life as of December 31, 2021, which resulted in the immediate recognition of $1.7 million of other revenue that had previously been deferred.

Cost of Goods Sold

During the year ended December 31, 2022, cost of goods sold was relatively flat at $0.7 million for both 2022 and 2021.

Research and Development Expenses

For the year ended December 31, 2022, research and development expenses increased to $18.6 million from $13.8 million for the year ended December 31, 2021, an increase of $4.8 million or 35%. The increase is primarily due to higher expenses for preparation of the pre-NDA meeting in April 2022 and increased third party expenses related to the NDA resubmission which occurred on February 14, 2023.

Selling, General and Administrative Expenses

For the year ended December 31, 2022, selling, general and administrative expenses increased to $17.3 million from $13.6 million for the year ended December 31, 2021, an increase of $3.7 million or 27%. The increase is primarily higher costs incurred for the preparation of commercialization of HEPZATO in the United States in 2023 and the estimated accrual for the settlement of the medac litigation.

Interest Expense, Net

For the year ended December 31, 2022, we recognized $2.7 million of interest expense, as compared to $1,2 million in the prior year, an increase of $1.5 million. The increase primarily relates to a full year of interest expense and amortization of debt discount associated with the Avenue loan which commenced on August 6, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America or GAAP. Certain critical accounting estimates have a significant impact on amounts reported in the consolidated financial statements. A summary of those critical accounting estimates is below. Additional details can be found in Note 3 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K.

Fair Value Measurements

GAAP 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, GAAP 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).

Our fair value measurements are generally related to a contingent liability and stock-based compensation. Contingent liabilities are re-measured to fair value each reporting period using projected financial targets, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected financial targets are based on our most recent internal operational budgets and may take into consideration alternate scenarios that could result in more or less profitability for the respective service line. Increases or decreases in projected financial targets and probabilities of payment may result in significant changes in the fair value measurements. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs in isolation may result in a significantly lower or higher fair value measurement.

Valuation of stock options generally requires certain assumptions, including the fair value of our common stock (generally an observable market price, as our common stock is publicly traded), the expected term of the financial instrument (judgment is required), the expected volatility of our common stock over the expected term (generally estimated by reference to the historical volatility of our common stock), our expected dividend rate over the expected term (currently estimated as zero, given that we are not projecting profits over the intermediate term) and the expected risk-free rate over the expected term (generally estimated by reference to United States treasury instruments with similar remaining terms).

Revenue Recognition

Revenue is generated from proprietary and partnered product sales and license and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

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

The Company recognizes revenue in accordance with ASC 606, Revenue from Contracts with Customers or ASC 606. The core principle of ASC 606 requires that an entity 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. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

The following five steps are applied to achieve that core principle:

Step 1: Identify the contract with the customer;

Step 2: Identify the performance obligations in the contract;

Step 3: Determine the transaction price, including an estimation of any variable consideration expected to be received in connection with the contract;

Step 4: Allocate the transaction price to the performance obligations in the contract; and

Step 5: Recognize revenue when the company satisfies a performance obligation.

Each of these steps in the revenue recognition process requires management to make judgments and/or estimates. The most significant judgements and estimates involve the determination of variable consideration to be included in the transaction price. Variable consideration is recognized at an amount we believe is not subject to significant reversal and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed. We believe this provides a reasonable basis for recognizing revenue; however, actual results could differ from estimates and significant changes in estimates could impact our results of operations in future periods.

As required by GAAP, the Company disaggregates its revenue into the categories of product revenue and other revenue. The Company recognizes product revenue and milestone payments at a point in time, whereas other revenues (primarily license fees) are recognized over time. Milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved.

Accrued Expenses

We utilize contract research organizations in order to perform research and development and conduct clinical trials. In some cases, these organization do not bill on a timely basis. Management monitors certain key drivers of these costs and estimates accruals in an attempt to properly match expenses incurred with the appropriate reporting period. However, there is judgment involved and the actual billings could be more or less than the estimated accrual.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the years ended December 31, 2022 and 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph—Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our 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 regarding 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 provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

Marcum LLP

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

New York, NY
March 27, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 7,671	$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	366	44
Inventories	1,998	1,412
Prepaid expenses and other current assets	1,969	2,743
Total current assets	16,155	31,152
Property, plant and equipment, net	1,422	1,348
Right-of-use assets	285	624
Total assets	$ 17,862	$ 33,124
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,018	$ 638
Accrued expenses	4,685	4,109
Deferred revenue	—	170
Lease liabilities, current	186	416
Loan payable, current	7,846	621
Total current liabilities	14,735	5,954
Other liabilities, non-current	1,144	207
Loan payable, non-current	3,070	10,372
Convertible notes payable, non-current	4,772	4,639
Total liabilities	23,721	21,172
Commitments and contingencies	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 10,046,571 shares and 7,906,728 shares issued and outstanding at December 31, 2022 and 2021, respectively	100	79
Additional paid-in capital	451,608	432,831
Accumulated deficit	(457,484)	(420,976)
Accumulated other comprehensive (loss) income	(83)	18
Total stockholders' equity (deficit)	(5,859)	11,952
Total liabilities and stockholders' equity (deficit)	$ 17,862	$ 33,124

See Accompanying Notes to these Consolidated Financial Statements.

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

	Year ended December 31,	
	2022	**2021**
Product revenue	$ 2,548	$ 1,300
Other revenue	171	2,255
Total revenues	2,719	3,555
Cost of goods sold	(686)	(671)
Gross profit	2,033	2,884
Operating expenses:		
Research and development expenses	18,583	13,778
Selling, general and administrative expenses	17,303	13,637
Total operating expenses	35,886	27,415
Operating loss	(33,853)	(24,531)
Interest expense, net	(2,685)	(1,186)
Other income	30	68
Net loss	(36,508)	(25,649)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	101	122
Total other comprehensive loss	$ (36,407)	$ (25,527)
Common share data:		
Basic and diluted loss per common share	$ (4.12)	$ (3.59)
Weighted average number of basic and diluted shares outstanding	8,864,615	7,145,754

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share and per share data)

	Year ended December 31, 2022							
	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2022	11,357	$—	7,906,728	$ 79	$432,831	$(420,976)	$ 18	$ 11,952
Compensation expense for issuance of stock options	—	—	—	—	7,941	—	—	7,941
Private placement - issuance of common shares and prefunded warrants, net of expenses	—	—	2,139,843	21	10,836	—	—	10,857
Net loss	—	—	—	—	—	(36,508)	—	(36,508)
Total comprehensive loss	—	—	—	—	—	—	(101)	(101)
Balance at December 31, 2022	11,357	$—	10,046,571	$100	$451,608	$(457,484)	$ (83)	$ (5,859)

DELCATH SYSTEMS, INC.
Consolidated Statements of Stockholders' Equity (Deficit), Continued
(in thousands, except share and per share data)

	Year Ended December 31, 2021							
	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2021	20,631	$ —	5,996,101	$ 60	$417,449	$(395,327)	$(104)	$ 22,078
Compensation expense for issuance of stock options	—	—	—	—	7,832	—	—	7,832
Shares settled for services	—	—	2,636	—	57	—	—	57
Conversion of preferred stock into common stock	(9,274)	—	927,379	9	(9)	—	—	—
Exercise of warrants into common stock	—	—	465,173	5	2,453	—	—	2,458
Proceeds allocated to warrant	—	—	—	—	1,171	—	—	1,171
Cash issuance costs of warrant	—	—	—	—	(44)	—	—	(44)
Exercise of options into common stock	—	—	439	—	4	—	—	4
Common stock issued in connection with ATM Offering	—	—	515,000	5	3,918	—	—	3,923
Net loss	—	—	—	—	—	(25,649)	—	(25,649)
Total comprehensive income	—	—	—	—	—	—	122	122
Balance at December 31, 2021	11,357	$—	7,906,728	$ 79	$432,831	$(420,976)	$ 18	$ 11,952

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows
(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$(36,508)	$(25,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	7,941	7,832
Depreciation expense	132	146
Non-cash lease expense	443	322
Amortization of debt discount	768	323
Interest expense accrued related to convertible notes	160	186
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	774	813
(Increase) decrease in accounts receivable	(322)	13
Increase in inventories	(587)	(557)
Increase (decrease) in accounts payable and accrued expenses	1,798	(3,284)
Increase (decrease) in other liabilities, non-current	621	(322)
Decrease in deferred revenue	(170)	(2,427)
Net cash used in operating activities	(24,950)	(22,604)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(209)	(143)
Net cash used in investing activities	(209)	(143)
Cash flows from financing activities:		
Net proceeds from private placement	10,857	—
Net proceeds from ATM offering		3,923
Net proceeds from debt financing	—	14,437
Proceeds from the exercise of stock options		4
Proceeds from the exercise of warrants	—	2,458
Payment of loan payable	(714)	
Net cash provided by financing activities	10,143	20,822
Foreign currency effects on cash	(115)	122
Net decrease in total cash	(15,131)	(1,803)
Total Cash, Cash Equivalents and Restricted Cash:		
Beginning of period	26,953	28,756
End of period	$ 11,822	$ 26,953
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash	$ 7,671	$ 22,802
Restricted Cash	4,151	4,151
Total	$ 11,822	$ 26,953

DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows, continued
(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$1,873	$ 681
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Issuance of restricted stock for accrued fees due to a former Board member	$ —	$ 57
Proceeds allocated to warrant	$ —	$1,171
Financing of D&O insurance premium		$ 886
Right of use assets obtained in exchange for lease obligations	$ 86	$ —

See Accompanying Notes to these Consolidated Financial Statements.

(1) Description of Business

Delcath Systems, Inc. ("Delcath" or the "Company") is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The Company's lead product candidate, the HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO™, is a drug/device combination product. HEPZATO is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our commercial product is a stand-alone medical device having the same device components as the HEPZATO KIT, but without the melphalan hydrochloride, and is approved for sale under the trade name CHEMOSAT® Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

The Company's clinical development program for HEPZATO was comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial investigating objective response rate in metastatic ocular melanoma, or mOM, a type of primary liver cancer. The Company is currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications which will maximize the value of the HEPZATO platform.

In the United States, HEPZATO is considered a combination drug and device product regulated by the Food and Drug Administration (the "FDA"). Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the hepatocellular carcinoma indication). HEPZATO has not been approved for sale in the United States.

In December 2021, the Company announced that the FOCUS Trial of HEPZATO met its pre-specified endpoint. On February 14, 2023 filed a New Drug Application resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023.

The resubmission is in response to a September 12, 2013 Complete Response Letter (CRL) from the FDA. The NDA resubmission contains comprehensive data and information relating to the matters identified in the CRL. We continue to promote our early access programs in the United States to make HEPZATO readily available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States. There are currently patients enrolled in our early access program sites.

On February 28, 2022, CHEMOSAT received Medical Device Regulation certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, the Company has assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Risks and Uncertainties

Although the Company is not aware of any direct impacts of the war between the Ukraine and the Russian Federation on its supply chain, the war could adversely impact the Company's ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its

(1) Description of Business – Continued

Risks and Uncertainties – Continued

third-party suppliers in a timely manner or at all. In addition, at this time, although the Company is not aware of any direct impacts, any increase in COVID cases and associated restrictions, could adversely impact the Company's ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its third-party suppliers in a timely manner or at all. Any rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company's ability to meet anticipated timelines.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, during the year ended December 31, 2022, the Company incurred net losses of $36.5 million and used $25.0 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.

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock and 566,751 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $3.98 and the pre-funded warrants were sold at a price of $3.97 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $5.0 million before deducting offering expenses.

On December 13, 2022, the Company closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $2.90 and the pre-funded warrants were sold at a price of $2.89 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $6.2 million before deducting offering expenses.

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 the Company 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 its 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 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 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. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. 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

(1) Description of Business – Continued

Liquidity and Going Concern – Continued

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 the Company. All significant inter-company accounts and transactions are eliminated.

(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 valuation of warrants, 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; 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.

(3) Summary of Significant Accounting Policies – Continued

Inventories

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

Property, Plant and Equipment

Property, plant, and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight-line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. The Company evaluates property, plant and equipment for impairment periodically to determine if changes in circumstances or the occurrence of events suggest the carrying value of the asset or asset group may not be recoverable. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Fair Value Measurements

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

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

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can 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

(3) Summary of Significant Accounting Policies – Continued

Fair Value Measurements – Continued

measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

Revenue Recognition

Revenue is generated from proprietary and partnered product sales and license and royalty arrangements. Revenue is recognized when or as the Company transfers control of the promised goods or services to its customers in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods or services. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

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

The Company recognizes revenue in accordance with ASC 606, Revenue from Contracts with Customers ("ASC 606"). The core principle of ASC 606 requires that an entity 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. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer;
- Step 2: Identify the performance obligations in the contract;
- Step 3: Determine the transaction price, including an estimation of any variable consideration expected to be received in connection with the contract;
- Step 4: Allocate the transaction price to the performance obligations in the contract; and
- Step 5: Recognize revenue when the company satisfies a performance obligation.

Each of these steps in the revenue recognition process requires management to make judgments and/or estimates. The most significant judgements and estimates involve the determination of variable consideration to be included in the transaction price. Variable consideration is recognized at an amount management believes is not subject to significant reversal and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed. Management believes this provides a reasonable basis for recognizing revenue; however, actual results could differ from estimates and

(3) Summary of Significant Accounting Policies – Continued

Revenue Recognition – Continued

significant changes in estimates could impact the Company's results of operations in future periods.

As required by ASC 606, the Company disaggregates its revenue into the categories of product revenue and other revenue. The Company recognizes product revenue and milestone payments at a point in time, whereas other revenues (primarily license fees) are recognized over time. Milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved. See Note 13 – Commitments and Contingencies – Litigations, Claims and Assessments – medac Matter.

Deferred Revenue

The timing of the Company's revenue recognition may differ from the timing of payment by its customers. A receivable is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, the Company records deferred revenue until the performance obligations are satisfied. See Note 13 – Commitments and Contingencies – Litigations, Claims and Assessments – medac Matter.

Selling, General and Administrative

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

Research and Development

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

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, Stock-Based Compensation, which establishes accounting for equity instruments exchanged for 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 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

(3) Summary of Significant Accounting Policies – Continued

Stock Based Compensation – Continued

market value of the 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 option, the expected term, the expected volatility of the stock over the option's expected term, the risk-free interest rate over the option's expected term, and the expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the ASC 740 "Income Taxes." Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company applies the accounting guidance issued to address the accounting for uncertain tax positions. This guidance clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements as well as provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company classifies interest and penalty expense related to uncertain tax positions as a component of income tax expense. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. See Note 14 for additional information.

Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities, except for those shares that are issuable for little or no cash consideration. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options, stock purchased pursuant to the Company's employee stock purchase plan, convertible notes 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.

(amounts in thousands, except share and per share amounts)

(3) Summary of Significant Accounting Policies – Continued

Net Loss per Common Share – Continued

For the years ended December 31, 2022 and 2021 the following potentially dilutive securities were excluded from the computation of diluted earnings per share because their effects would be antidilutive:

	December 31,	
	2022	2021
Common stock warrants - equity	3,610,743	3,610,743
Assumed conversion of Series E and Series E-1 Preferred Stock	1,135,721	1,135,721
Assumed conversion of convertible notes	488,031	488,031
Stock options	2,235,052	1,732,460
Total	7,469,547	6,966,955

Segment Information

A single management team that reports to the Chief Executive Officer comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Foreign Currency and Currency Translation

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

The assets and liabilities of the Company's international subsidiaries are translated from their functional currencies into United States dollars at exchange rates prevailing at the balance sheet date. The majority of the foreign subsidiaries revenues and operating expenses are denominated in Euros. The reporting currency for the Company is the United States dollar. 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.

Subsequent Events

Management has evaluated events occurring subsequent to the consolidated balance sheet date, through March 27, 2023, which is the date the consolidated financial statements were issued, determining all subsequent events have been disclosed.

Recently Adopted and Issued Accounting Pronouncements

We have not been required to adopt any accounting standards that had a significant impact on our consolidated financial statements in the two years ended December 31, 2022. We do not expect any recently issued accounting standards to have a significant impact on our consolidated financial statements.

(amounts in thousands, except share and per share amounts)

(4) Revision of Previously Issued Quarterly Financial Statements

In preparation of the Company's audited financial statements as of and for year ended December 31, 2022, the Company determined it needed to correct previously reported share-based compensation expense for each quarter during 2022. The correction for share-based compensation increased the net loss in amount of $797 for the first quarter of 2022, $502 for the second quarter of 2022 and $372 for the third quarter of fiscal 2022. The share-based compensation adjustment is a non-cash adjustment did not have any impact on the cash balances for the Company.

The following tables contains the financial information for the periods previously reported and have been updated to reflect the revisions of the Company's financial statements. The revisions do not have an impact on the Company's cash position The Company has not amended its previously filed Quarterly Reports on Form 10-Q for the three quarterly periods ended September 30, 2022. The financial information that has been previously filed or otherwise reported for the three quarterly periods ended September 30, 2022 is superseded by the information in this Quarterly Report on Form 10-Q, and the financial statements and related financial information for the quarterly periods ended September 30, 2022 contained in such previously filed report should no longer be relied upon. The impact of the revision on the Company's financial statements is reflected in the following table:

	As previously report	Adjustment	As revised
Balance Sheet for March 31, 2022 (unaudited)			
Additional paid-in capital	$ 434,305	$ 797	$ 435,102
Accumulated deficit	(429,179)	(797)	(429,976)
Consolidated Statement of Operations and Comprehensive Loss for the three months March 31, 2022 (unaudited)			
Research and development expenses	4,240	241	4,481
Selling, general and administrative expenses	3,648	556	4,204
Total operating expenses	7,888	797	8,685
Operating loss	(7,543)	(797)	(8,340)
Net loss	(8,203)	(797)	(9,000)
Total other comprehensive loss	(8,201)	(797)	(8,998)
Basic and diluted loss per common share	(1.00)	(0.10)	(1.10)
Consolidated statement of Stockholders' Equity (Deficit) for the three months ended March 31, 2022 (unaudited)			
Compensation expense for issuance of stock options	1,474	797	2,271
Net loss	(8,203)	(797)	(9,000)
Consolidated Statement of Cash Flows for the three months ended March 31, 2022 (unaudited)			
Net loss	(8,203)	(797)	(9,000)
Stock option compensation expense	1,474	797	2,271
Balance Sheet for June 30, 2022 (unaudited)			
Additional paid-in capital	435,922	1,299	437,221
Accumulated deficit	(438,836)	(1,299)	(440,135)

(amounts in thousands, except share and per share amounts)

(4) Revision of Previously Issued Quarterly Financial Statements – Continued

	As previously report	Adjustment	As revised
Consolidated Statement of Operations and Comprehensive Loss for the three months June 30, 2022 (unaudited)			
Research and development expenses	5,456	150	5,606
Selling, general and administrative expenses	4,145	352	4,497
Total operating expenses	9,601	502	10,103
Operating loss	(8,984)	(502)	(9,486)
Net loss	(9,657)	(502)	(10,159)
Total other comprehensive loss	(9,688)	(502)	(10,190)
Basic and diluted loss per common share	(1.18)	(0.06)	(1.24)
Consolidated statement of Stockholders' Equity (Deficit) for the three months ended June 30, 2022 (unaudited)			
Compensation expense for issuance of stock options	1,617	502	2,119
Net loss	(9,657)	(502)	(10,159)
Balance Sheet for September 30, 2022 (unaudited)			
Additional paid-in capital	442,066	1,671	443,737
Accumulated deficit	(447,341)	(1,671)	(449,012)
Consolidated Statement of Operations and Comprehensive Loss for the three months September 30, 2022 (unaudited)			
Research and development expenses	3,953	112	4,065
Selling, general and administrative expenses	4,519	260	4,779
Total operating expenses	8,472	372	8,844
Operating loss	(7,801)	(372)	(8,173)
Net loss	(8,505)	(372)	(8,877)
Total other comprehensive loss	(8,551)	(372)	(8,923)
Basic and diluted loss per common share	(0.92)	(0.04)	-0.96
Consolidated statement of Stockholders' Equity (Deficit) for the three months ended September 30, 2022 (unaudited)			
Compensation expense for issuance of stock options	1,255	372	1,627
Net loss	(8,505)	(372)	(8,877)
Consolidated Statement of Operations and Comprehensive Loss for the six months June 30, 2022 (unaudited)			
Research and development expenses	9,696	391	10,087
Selling, general and administrative expenses	7,791	908	8,699
Total operating expenses	17,487	1,299	18,786
Operating loss	(16,527)	(1,299)	(17,826)
Net loss	(17,860)	(1,299)	(19,159)
Total other comprehensive loss	(17,889)	(1,299)	(19,188)
Basic and diluted loss per common share	(2.18)	(0.16)	(2.34)

(amounts in thousands, except share and per share amounts)

(4) Revision of Previously Issued Quarterly Financial Statements – Continued

	As previously report	Adjustment	As revised
Consolidated Statement of Cash Flows for the six months ended June 30, 2022 (unaudited)			
Net loss	(17,860)	(1,299)	(19,159)
Stock option compensation expense	3,091	1,299	4,390
Consolidated Statement of Operations and Comprehensive Loss for the nine months September 30, 2022 (unaudited)			
Research and development expenses	13,649	503	14,152
Selling, general and administrative expenses	12,309	1,168	13,477
Total operating expenses	25,958	1,671	27,629
Operating loss	(24,327)	(1,671)	(25,998)
Net loss	(26,365)	(1,671)	(28,036)
Total other comprehensive loss	(26,447)	(1,671)	(28,118)
Basic and diluted loss per common share	(3.09)	(0.20)	(3.29)
Consolidated Statement of Cash Flows for the nine months ended September 30, 2022 (unaudited)			
Net loss	(26,365)	(1,671)	(28,036)
Stock option compensation expense	4,345	1,671	6,016

(5) Cash, Cash Equivalents and Restricted Cash

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 7,671	$22,802
Restricted balance for loan agreement	4,000	4,000
Letters of credit	101	101
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$11,822	$26,953

Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, as of December 31, 2022, the Company is required to maintain a letter of credit in the amount of $101, which will expire with the sublease in May 2023. On March 15, 2023, the Company returned to Avenue the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance.

(amounts in thousands, except share and per share amounts)

(6) Inventories

Inventories consist of:

	December 31, 2022	December 31, 2021
Raw materials	$ 763	$ 767
Work-in-process	1,102	645
Finished goods	133	—
Total inventories	$1,998	$1,412

(7) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

	December 31, 2022	December 31, 2021
Clinical trial expenses	$1,630	$1,630
Insurance premiums	123	890
Professional services	121	15
Other	95	208
Total prepaid expenses and other current assets	$1,969	$2,743

(8) Property, Plant, and Equipment

Property, plant, and equipment consists of:

	December 31, 2022	December 31, 2021	Estimated Useful Life
Buildings and land	$ 1,301	$ 1,222	30 years - Buildings
Enterprise hardware and software	1,855	1,858	3 years
Leaseholds	1,774	1,796	Lesser of lease term or estimated useful life
Equipment	1,222	1,094	7 years
Furniture	201	203	5 years
Property, plant and equipment, gross	6,353	6,173	
Accumulated depreciation	(4,931)	(4,825)	
Property, plant and equipment, net	$ 1,422	$ 1,348	

Depreciation expense for the years ended December 31, 2022 and 2021 was $132 and $146, respectively.

(amounts in thousands, except share and per share amounts)

(9) Accrued Expenses

Current accrued expenses include the following:

	December 31, 2022	December 31, 2021
Clinical expenses	$1,470	$1,517
Compensation, excluding taxes	1,040	893
Short-term financing	—	551
Professional fees	1,087	603
Interest on convertible note	553	393
Other	535	152
Total accrued expenses	$4,685	$4,109

(10) Leases

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

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

Pursuant to a 2014 sublease agreement (the "2014 Sublease") and a 2015 sublease agreement (the "2015 Sublease") the Company subleased portions of its leased premises in Galway, Ireland to a sublessee. On May 15, 2020, the Company and its sublessee entered into amendments to the 2014 Sublease and the 2015 Sublease pursuant to which (i) the 2014 Sublease and 2015 Sublease were extended from May 31, 2020 to August 2, 2021, (ii) effective July 1, 2020, the leased premises under the 2015 Sublease would be expanded to include an additional 4,999 square feet of space, and (iii) effective July 1, 2020, the rent under the 2015 Sublease would increase from approximately $14.6 per month to $20.6 per month. The Company analyzed the terms of the amended 2014 Sublease and 2015 Sublease and determined that its ROU asset for the master operating lease was not impaired as a result of the amendments. On June 25, 2020, the Company entered into a sublease agreement (the "2021 Sub-Lease") with its previous sublessee under the 2014 Sublease and 2015 Sublease pursuant to which, effective August 2, 2021, the previous sublessee would become the lessee and the Company would then sublease its portion of the premises in Galway, Ireland from the previous sublessee. The Company's rent expense under the 2021 Sub-Lease is approximately $3.7 per month for a term of five years.

On September 22, 2020, the Company entered into an amendment to a sub-lease agreement executed in March 2016 for approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term of the sub-lease agreement began in April 2016 and, pursuant to the amendment on November 2022, is extended through May 2023.

(amounts in thousands, except share and per share amounts)

(10) Leases – Continued

The following table summarizes the Company's operating leases as of December 31, 2022:

	U.S.	Ireland	Total
Lease cost			
Operating lease cost	$ 406	$ 37	$ 443
Other information			
Operating cash flows out from operating leases	(406)	(37)	(443)
Weighted average remaining lease term	0.5	3.6	
Weighted average discount rate - operating leases	8%	8%	

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

	U.S.	Ireland	Total
Year ended December 31, 2023	155	37	192
Year ended December 31, 2024	—	37	37
Year ended December 31, 2025	—	37	37
Year ended December 31, 2026	—	22	22
Total	155	133	288
Less present value discount	(3)	(17)	(20)
Operating lease liabilities included in the condensed consolidated balance sheets at December 31, 2022	$152	$116	$268

(11) Loans and Convertible Notes Payable

	December 31, 2022			December 31, 2021		
	Gross	Discount	Net	Gross	Discount	Net
Loan - Avenue [1]	$11,923	$(1,008)	$10,916	$12,638	$(1,645)	$10,993
Loan - Avenue [1] - Less Current Portion	(8,570)	724	(7,846)	(714)	93	(621)
Total - Loans Payable, Non-Current	$ 3,353	$ (284)	$ 3,070	$11,924	$(1,552)	$10,372
Convertible Note Payable - Rosalind	2,000	—	2,000	2,000	—	2,000
Convertible Portion of Loan Payable - Avenue	3,000	(228)	2,772	3,000	(361)	2,639
Total - Convertible Notes Payable - Non-Current	$ 5,000	$ (228)	$ 4,772	$ 5,000	$ (361)	$ 4,639

[1] The gross amount includes the 4.25% final payment of $637.5.

Remaining maturities of the Company's loan and convertible note payables are as follows:

	Loans	Convertible Notes	Total
Year ended December 31, 2023	$ 8,570	$ —	$ 8,570
Year ended December 31, 2024	3,353	5,000	8,353
Total	$11,923	$5,000	$16,923

(11) Loans and Convertible Notes Payable – Continued

Term Loan from Avenue Venture Opportunities Fund, L.P.

On August 6, 2021, the Company entered into a Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue") for a term loan in an aggregate principal amount of up to $20.0 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.70% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at December 31, 2022 was 15.2%. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024.

The initial tranche of the Avenue Loan is $15.0 million, including $4.0 million which has been funded into a restricted account and will be released upon achievement of (a)(x) positive FOCUS trial efficacy per the trial's predefined Statistical Analysis Plan (SAP) (specifically the Overall Response Rate exceeds the prespecified threshold for success defined in the SAP by a statistically significant amount); and (y) based on data contained within the FOCUS trial database and appropriate for use with the U.S. Food and Drug Administration, safety and tolerability among FOCUS trial participants is within the range of currently approved and commonly used cytotoxic chemotherapeutic agents; and (b) raising subsequent net equity proceeds of at least $20.0 million. The Company may request an additional $5.0 million of gross proceeds between October 1, 2022 and December 31, 2022, with funding, subject to the approval of Avenue's Investment Committee. Since the Company did not achieve a net equity raise of $20.0 million of gross proceeds, the Company did not request an additional $5.0 million of funding during the period from October 1, 2022 through December 31, 2022.

Up to $3.0 million of the principal amount of the Avenue Loan outstanding may be converted, at the option of Avenue, into shares of the Company's common stock at a conversion price of $11.98 per share.

In connection with the Avenue Loan, the Company issued to Avenue a warrant (the "Avenue Warrant") to purchase 127,755 shares of common stock at an exercise price per share equal to $0.01. The Avenue Warrant is exercisable until August 31, 2026.

The Company will make monthly interest-only payments during the first fifteen months of the term of the Avenue Loan, which could be increased to up to twenty-four months upon the achievement of specified performance milestones. Following the interest-only period, the Company will make equal monthly payments of principal plus interest until the maturity date, when all remaining principal outstanding and accrued interest must be paid. The interest only period ended in November 2022, and the Company began making principal payments on December 1, 2022. If the Company prepays the Avenue Loan, it will be required to pay (a) a prepayment fee of 3% if the Avenue Loan is prepaid during the interest-only period; and (b) a prepayment fee of 1% if the Avenue Loan is prepaid after the interest-only period. The Company must make an incremental final payment equal to 4.25% of the aggregate funding. On March 15, 2023, the Company returned to Avenue the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance and reduce the monthly principal payments.

The Company paid an aggregate commitment fee of $150 at closing. Upon funding a second tranche of the Avenue Loan, the Lender will earn a 1.0% fee on the $5.0 million of incremental committed capital, for a total commitment fee of $200.

(amounts in thousands, except share and per share amounts)

(11) Loans and Convertible Notes Payable – Continued

Term Loan from Avenue Venture Opportunities Fund, L.P. – Continued

The Avenue Loan Agreement requires the Company to make and maintain representations and warranties and other agreements that are customary in loan agreements of this type. The Avenue Loan Agreement also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy and material judgments.

The Company determined that the embedded conversion option associated with the Avenue Loan was not required to be bifurcated. The Company determined that the Avenue Warrant met the criteria to be equity-classified. The $637 value of the final payment was treated as original issue discount. The $1,171 relative fair value of the Avenue Warrant was credited to Additional Paid in Capital while it was debited as debt discount. Of the $563 of cash issuance costs, $519 was allocated to the Avenue Loan and was recorded as debit discount, while $44 was allocated to the Avenue Warrant and was debited to Additional Paid in Capital. Of the $2,327 of aggregate debt discount, $1,909 was allocated to the non-convertible portion of the Avenue Loan, while $418 was allocated to the convertible portion of the Avenue Loan. Aggregate debt discount amortization of $0.8 million was recorded during the year ended December 31, 2022. The Company also determined that the convertible portion of the Avenue Loan did not include a beneficial conversion feature, because the effective conversion price exceeded the commitment date market price of the Company's common stock. Interest expense was $1.9 million for the year ended December 31, 2022.

The Avenue Warrant was valued at issuance at $1.3 million using the Black-Scholes option pricing method using the following assumptions:

	August 6, 2021
Contractual term (years)	5.07
Expected volatility	187.0%
Risk-free interest rate	0.77%
Expected dividends	0.00%

Convertible Notes Payable

The Company has $2.0 million of principal outstanding related to Senior Secured Promissory Notes (the "Rosalind Notes") which bear interest at 8% per annum. Pursuant to their original terms, the Rosalind Notes were convertible into Series E Preferred Stock at a price of $1,500 per share and were to mature on July 16, 2021**.**

On August 6, 2021, the Company executed an agreement to amend the Rosalind Notes to (a) reduce the conversion price to $1,198 per share of the Company's Series E Convertible Preferred Stock; and (b) extend the maturity date to October 30, 2024.

In addition, in order to induce the Avenue Venture Opportunities Fund, L.P. to provide the Avenue Loan described above, the holders of the Rosalind Notes agreed to subordinate (a) all of the Company's indebtedness and obligations to the holders; and (b) all of the holders' security interest, to the Avenue Loan and Avenue's security interest in the Company's property.

Up to $3.0 million of the principal amount of the Avenue Loan outstanding may be converted, at the option of the Lender, into shares of the Company's common stock at a conversion price of $11.98 per share.

Interest expense with respect to the Rosalind Notes was $160 for both years ended December 31, 2022 and 2021

(12) Stockholders' Equity

Authorized Shares

The Company is authorized to issue 40,000,000 shares of common stock, $0.01 par value, and 10,000,000 shares of preferred stock, $0.01 par value. To date, the Company has designated the following preferred stock: Series A (4,200 shares), Series B (2,360 shares), Series C (590 shares), Series D (10,000 shares), Series E (40,000 shares) and Series E-1 (12,960 shares).

Preferred Stock

Series E and Series E-1 Convertible Preferred Stock

During the years ended December 31, 2021, 9,274 shares of Series E and Series E-1 Convertible Preferred Stock were converted into 927,379 shares of the Company's common stock.

As of December 31, 2022, there were an aggregate of 11,357 shares of Series E and Series E-1 Convertible Preferred Stock outstanding.

Equity Offerings and Placements

At-the-Market Offering

On August 18, 2020, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, as sales agent or principal, shares of the Company's common stock, (the "Placement Shares"), having an aggregate offering price of up to $10 million (the "ATM Offering"). On November 9, 2021 the Company filed a supplement to increase the aggregate amount to $25 million. On February 27, 2023, filed an amendment to change the aggregate offering price to the limit of $17 million.

The Company has no obligation to sell any Placement Shares under the sales agreement. Subject to the terms and conditions of the sales agreement, Cantor Fitzgerald is required to use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Stock Market, to sell Placement Shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of Placement Shares, reimburse Cantor Fitzgerald's legal fees and disbursements up to $50 and provide Cantor Fitzgerald with customary indemnification and contribution rights. The sales agreement may be terminated by Cantor Fitzgerald or the Company upon notice to the other party as provided in the sales agreement, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares.

In connection with the ATM Offering, in consideration for a fee equal to 1.05% of the gross sales price per share sold in the ATM Offering, ROTH Capital Advisors, LLC ("Roth") waived, solely with respect to the ATM Offering, (i) Roth's right, pursuant to certain engagement letters dated August 14, 2019 and January 13, 2020 between Roth and the Company, to act as placement agent or underwriter with respect to offerings of the Company's securities and to receive a minimum of 35% of the fees paid to the agents or underwriters for such offerings and (ii) the lock-up provision included in a certain underwriting agreement dated May 1, 2020 between Roth and the Company requiring the prior written consent of Roth for any offer or sale of the Company's common stock by the Company during the 90-day period following the date of such underwriting agreement.

(12) Stockholders' Equity – Continued

Equity Offerings and Placements – Continued

At-the-Market Offering – Continued

During the year ended December 31, 2021, the Company sold 515,000 shares of common stock pursuant to the ATM Offering for aggregate gross proceeds of $4.0 million, partially offset by $121 of issuance costs. There were no shares sold year ended December 31, 2022.

Private Placement

On July 20, 2022, the Company closed a private placement for the issuance and sale of 690,954 shares of common stock and 566,751 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $3.98 and the pre-funded warrants were sold at a price of $3.97 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $5.0 million before deducting offering expenses.

On December 13, 2022, the Company closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $2.90 and the pre-funded warrants were sold at a price of $2.89 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $6.2 million before deducting offering expenses.

Other Common Stock Issuances

In February 2021, the Company issued 2,636 shares of unregistered common stock in lieu of a cash payment of deferred accrued director fees to a former director.

During the year ended December 31, 2021, the Company issued 465,173 shares of common stock associated with the exercise of warrants, including 215,000 pre-funded warrants at an exercise price of $0.01 per share, for aggregate cash proceeds of $2.5 million.

Stock Incentive Plans

The Company's 2019 Equity Incentive Plan (the "2019 Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants, and advisors are eligible to receive grants under the 2019 Plan. The 2019 Plan provides for the grant of options to purchase shares of common stock at exercise prices not less than 100% of fair value on the dates of grant. The maximum number of shares reserved for issuance under the 2019 Plan was 2,142. The 2019 Plan has been superseded by the 2020 Plan discussed below and no further awards will be made under the 2019 Plan; however, outstanding awards granted under the 2019 Plan will remain outstanding and continue to be administered in accordance with the terms of the 2019 Plan and the applicable award agreements.

On September 30, 2020, the Company's 2020 Omnibus Equity Incentive Plan (the "2020 Plan") was adopted by the Company's Board of Directors. On November 23, 2020, the Company's stockholders approved the 2020 Plan. The 2020 Plan will continue in effect until the tenth anniversary of the date of its adoption by the Board or until earlier terminated by the Board. The 2020 Plan is administered by the Board of Directors or a committee designated by the Board of Directors. The 2020 Plan provides for the grant of

(amounts in thousands, except share and per share amounts)

(12) Stockholders' Equity – Continued

Stock Incentive Plans – Continued

incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed to be consistent with the purposes of the plan to Company employees, directors and consultants. As of December 31, 2022, there are 2,475,000 shares of common stock reserved under the 2020 Plan, of which 870,508 remained available to be issued.

Stock Options

The Company values stock options using the Black-Scholes option pricing model and used the following assumptions during the reporting periods:

	Years Ended December 31	
	2022	2021
Expected terms (years)	0.7 - 8.4	5.1 - 6.3
Expected volatility	166.4% -180.3%	177.% - 181.3%
Risk-free interest rate	1.2% - 4.4%	0.7% - 1.3%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2022 and 2021 was approximately $6.05 and $9.74 per share, respectively.

The following is a summary of stock option activity for the year ended December 31, 2022:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	1,732,460	$11.69		
Granted	702,583	6.74		
Expired	(65,690)	10.43		
Cancelled/Forfeited	(134,301)	9.59		
Outstanding at December 31, 2022	2,235,052	$10.30	8.0	$ 36
Exercisable at December 31, 2022	1,316,515	$11.13	7.6	$—

The following table summarizes information for stock option shares outstanding and exercisable at December 31, 2022:

		Options Exercisable	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
$6.24 - $53.85	2,234,553	8.0	1,316,016
$53.85+	499	6.1	499
	2,235,052	7.6	1,316,515

(amounts in thousands, except share and per share amounts)

(12) Stockholders' Equity – Continued

Stock Options – Continued

At December 31, 2022, there was approximately $2.8 million of aggregate unrecognized compensation expense related to employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 1.6 years. For the years ended December 31, 2022 and 2021, the Company recognized compensation expense $7.9 million and $7.8 million, respectively, related to stock options granted to employees and board members, which were charged to the statement of operations as detailed below:

	Years Ended December 31,	
	2022	2021
Selling, general and administrative	$5,282	$ 5,334
Research and development	2,449	2,311
Cost of goods sold	210	187
Total	$7,941	$ 7,832

Employee Stock Purchase Plan

In August 2021, the Company's Board of Directors, with shareholder approval in May 2022, adopted the Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for a maximum of 260,295 shares of common stock to be purchased by participating employees. Employees who elect to participate in the ESPP will be able to purchase common stock at the lower of 85% of the fair market value of common stock on the first or last day of the applicable six-month offering period. In January 2023, an aggregate 15,417 shares were purchased by participating employees for the offering period of July 1, 2022 to December 31, 2022. The fair value of each ESPP award of $2.23 was estimated on the first day of the offering period using the Black-Scholes option-pricing model. The Company recognized share-based compensation expense of $34, which is equal to the fair value of the ESPP awards on a straight-line basis over the offering period.

Warrants

The following is a summary of warrant activity for the year ended December 31, 2022:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2022	3,894,498	$ 9.27	
Warrants issued	1,258,793	.01	
Outstanding at December 31, 2022	5,153,291	$ 7.01	2.8
Exercisable at December 31, 2022	5,153,291	$ 7.01	2.8

(amounts in thousands, except share and per share amounts)

(12) Stockholders' Equity – Continued

Warrants – Continued

The following table presents information related to stock warrants at December 31, 2022:

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$0.01	1,542,548	4.4	1,542,548
$10.00	3,610,743	2.2	3,610,743
	5,153,291	2.8	5,153,291

(13) Commitments and Contingencies

Litigation, Claims and Assessments

Former Officers Matter

Following the May 18, 2020 resignation (effective June 1, 2020) of Jennifer Simpson, the Company's former President and Chief Executive Officer, and Barbra Keck, the Company's former Chief Financial Officer (the "Claimants"), it became evident that there was a dispute regarding the Company's compensation obligations to the Claimants. In a letter dated, June 29, 2020, an attorney representing the Claimants made certain claims and threatened litigation against the Company. On or about July 27, 2020, the Claimants filed a statement of claim with the American Arbitration Association against the Company. The Claimants sought payment of certain purported unpaid compensation amounts claimed to be due to them, in an approximate amount of $1.1 million in the aggregate, as well as unspecified statutory damages under New York Labor Law, attorneys' fees and costs, and statutory interest. The Claimants and the Company agreed to participate in non-binding mediation of their dispute before a neutral mediator, which resulted in the arbitration proceedings being placed in abeyance pending the outcome of the mediation process. With the assistance of the neutral mediator and after careful consideration by the Company's board of directors following several weeks of negotiations, the Claimants and the Company agreed in mid-May of 2021 to a confidential settlement of their dispute to avoid the expenses and distractions of further arbitration proceedings, with no admission of liability or wrongdoing on the part of the Company. While the Company had accrued for the full purported unpaid compensation amount of $1.1 million as of December 31, 2020, the Company ultimately paid less in full and final settlement of its dispute with both of the Claimants. As a result of the confidential settlement, the AAA Arbitration was dismissed with prejudice on June 1, 2021.

medac Matter

In April 2021, the Company's wholly-owned subsidiary, Delcath Systems Ltd, issued to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), an invoice for a €1 million milestone payment under a License, Supply and Marketing Agreement dated December 10, 2018 (the "medac Agreement") between medac and the Company. The medac Agreement provided to medac the exclusive right to market and sell CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland and the United Kingdom for which the Company was entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

(13) Commitments and Contingencies – Continued

Litigation, Claims and Assessments – Continued

medac Matter – Continued

In response to medac's subsequent dispute and non-payment of the invoice, on October 12, 2021, the Company notified medac in writing that it was terminating the medac Agreement due to medac's nonpayment of the €1 million milestone payment, with the effective date of termination of the medac Agreement being April 12, 2022. medac disputed having an obligation to make the milestone payment and demanded withdrawal of the termination notice. In response to medac's continued failure to make the milestone payment and its demand for the Company to withdraw its termination notice, on December 16, 2021, we initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement. Thereafter, on December 30, 2021, we received a letter from medac stating that, due to our failure to withdraw the termination notice, medac was terminating the medac Agreement with immediate effect. In a separate letter, medac agreed to orderly transition through February 28, 2022 in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately $0.2 million. As a result of the early termination of the medac Agreement, the Company revised its estimate of the contract life which resulted in an acceleration of $1.7 million of revenue recognition associated with deferred revenue.

On December 30, 2022, the parties reached a final settlement of the matter and Delcath has agreed pay medac a royalty on sales of CHEMOSAT units over a defined minimum for a period of five years or until a maximum payment has been reached. The settlement terms also contain a minimum annual payment of $0.2 million in the event the annual royalty payment does not reach the agreed on minimum payment amount. The Company has estimated the settlement to be $1.2 million and recorded $1.0 million as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet and a $1.2 million charge in selling, general and administrative expenses in the Company's condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2022.

Lachman Consulting Services, Inc

On January 24, 2023, Lachman Consultant Services, Inc ("Lachman") served the Company with a Complaint alleging that Delcath owes Lachman approximately $900 in unpaid consulting fees plus interest, costs and attorneys' fees. The lawsuit is Lachman Consultant Services, Inc. v. Delcath Systems, Inc., Index No. 650103-2023 (New York Supreme Court, New York County. The Company filed an answer to Lachman's Complaint on February 22, 2023. On March 17, 2023, Delcath responded to Lachman's March 3, 2023 Motion for Partial Summary Judgment. On March 20, 2023, the Court denied Lachman's request that the case be moved into the Commercial Division. The current return date of Lachman's motion for partial summary judgment is March 31, 2023. The dispute arises from a July 22, 2021 agreement between Lachman and Delcath under which Lachman was to provide assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. In August 2022, the Company disputed $300 of charges from Lachman As of December 31, 2022, the Company has accrued $0.9 million as accrued liability on the Company's condensed consolidated balance sheet. The Company plans to vigorously defend this lawsuit and has reserved its rights to dispute all of Lachman charges as the litigation proceeds.

(amounts in thousands, except share and per share amounts)

(14) Income Taxes

There is no income tax provision for the years ended December 31, 2022 and 2021, respectively.

Loss before income taxes consists of:

	For the Year Ended December 31,	
	2022	2021
Domestic	$(34,547)	$(25,881)
Foreign	(1,960)	232
Income before taxes	$(36,507)	$(25,649)

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

	For the Year Ended December 31,	
	2022	2021
Income taxes using U.S federal statutory rate	$(7,666)	$(5,386)
Nondeductible interest	139	39
Loss of tax benefit of state net operating loss carryforwards	—	2,799
Branch income	(385)	229
State income taxes, net of federal benefit	(531)	311
Foreign rate differential	165	27
Valuation allowance	9,221	2,114
Stock option expense, exercises and cancellations	752	446
Research and development costs	(708)	(375)
Other	(987)	(204)
	$ —	$ —

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

	For the Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Employee compensation accruals	$ 2,772	$ 1,777
Accrued liabilities	197	29
Research tax credits	1,429	721
Lease obligation	38	107
Other	160	89
Research expense capitalization	3,203	—
Net operating losses	24,595	20,520
Total deferred tax assets	32,394	23,243

(amounts in thousands, except share and per share amounts)

(14) Income Taxes – Continued

	For the Year Ended December 31,	
	2022	2021
Deferred tax liabilities:		
Right of use asset	50	118
Total deferred tax liabilities	50	118
Valuation allowance	32,344	23,125
Net deferred tax assets	$ —	$ —

As of December 31, 2022, and 2021, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $290.4 million and $277.4 million, respectively. A significant portion of the federal amount is subject to an annual limitation as low as $28 as a result of changes in the Company's ownership in May 2003, November 2016, and multiple dates throughout 2017, 2018, 2019 and 2021, as defined by Section 382 of the United States Internal Revenue Code of 1986, as amended (the "IRC"), and the related income tax regulations. As a result of the limitations caused by the multiple ownership changes, approximately $202.6 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $87.7 million of net operating loss carryforwards remains available to offset future federal taxable income, of which $1.7 million will expire between 2023 and 2037 and $86.0 million will have an unlimited carryforward period.

In addition, the Company's state net operating losses are also subject to annual limitations that generally follow the IRC Section 382 provisions (with the exception of Connecticut and Florida), adjusted for each state's respective income apportionment percentages. As of December 31, 2022, and 2021, the Company had net operating loss carryforwards for states and city income tax purposes between approximately $0.3 million and $195.3 million and between approximately $24.8 million and $193.7 million, respectively, which expire through 2042. As a result of the Section 382 limitations, approximately $190.3 million and $174.5 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $5.1 million and $5.0 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2022 and 2021, the Company had a net operating loss carryforward for foreign income tax purposes of $33.4 million and $28.0 million, respectively, which have indefinite carryforward periods. As of December 31, 2022 and 2021, the Company had federal research and development tax credit carryforwards of approximately $6.5 million and $5.8 million, respectively, which expire through 2042. As a result of the Section 382 limitations, all but $1.4 million of the tax credit carryforwards is expected to expire unutilized.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company's valuation allowance increased by approximately $9.2 million and $1.8 million in 2022 and 2021, respectively. The change in valuation allowance is as follows:

	December 31,	
	2022	2021
Beginning Balance	$23,125	$21,332
Charged to costs and expenses	9,221	2,114
Charged to other comprehensive income	(2)	(321)
Ending balance	$32,344	$23,125

(amounts in thousands, except share and per share amounts)

(14) Income Taxes – Continued

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 roll forward of unrecognized tax benefits. As there are no uncertain tax positions recognized, interest and penalties have not been accrued.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by international tax authorities or any states in connection with income taxes. The Company's New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company is no longer subject to federal and state examination for tax years ending prior to December 31, 2019; tax years ending December 31, 2019 through December 31, 2022 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, 2018 (as Ireland has not initiated an audit of 2017 as of December 31, 2022); tax years ending December 31, 2018 through December 31, 2022 remain open to examination. However, the Company's tax years December 31, 1998 through December 31, 2022 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards a reutilized 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.

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

(15) Fair Value Measurements

The table below presents activity within Level 3 of the fair value hierarchy, our liabilities carried at fair value for the year ended December 31, 2022:

	Level 3
Balance at January 1, 2022	$ —
Add: contingent liability recorded on medac settlement	1,168
Change in exchange rate	112
Balance at December 31, 2022	$ 1,280

Contingent liabilities are re-measured to fair value each reporting period using projected financial targets, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected financial targets are based on our most recent internal operational budgets and may take into consideration alternate scenarios that could result in more or less profitability for the respective service line. Increases or decreases in projected financial

(amounts in thousands, except share and per share amounts)

(15) Fair Value Measurements – Continued

targets and probabilities of payment may result in significant changes in the fair value measurements. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs in isolation may result in a significantly lower or higher fair value measurement.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2022 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value. There were no financial assets and liabilities that have been measured at fair value as of December 31, 2021. In general, the fair values were determined using Level 3:

Description	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2021
Liabilities:				
Contingent Liability			$1,280	$1,280
Total Liabilities	$—	$—	$1,280	$1,280

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of its Chief Executive Officer and Chief Accounting Officer, performed an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act). Based on that evaluation, the Chief Executive Officer and Chief Accounting Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2022, because of the material weaknesses in internal control over financial reporting described below

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

We have performed an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on that evaluation, our management, including our Chief Executive Officer and Chief Accounting Officer, concluded that our internal control over financial reporting was not effective as of December 31, 2022, due to a material weakness in internal control over financial reporting on the detection and application of the Company's expense policy on its share-based compensation under the accelerated method.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Remediation Plans

We have commenced measures to remediate this material weakness and will design additional key controls in order to ensure the Company's share-based compensation is calculated under the accelerated method. We will continue to assess our finance and accounting staffing needs to ensure remediation of these material weakness. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We have begun to implement actions to remediate the material weakness described above. These remediation measures are ongoing and include designing and implementing new key controls to validate the information being reported on our share-based compensation software tool.

Changes in Internal Control Over Financial Reporting

During the most recently completed fiscal quarter, there have been changes to the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, its internal control over financial reporting, as described above.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. ***Directors, Executive Officers, and Corporate Governance***

The information required to be furnished pursuant to this Item will be set forth in our proxy statement for the 2023 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2022, and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available at the investors section of our website at *www.delcath.com*. Information contained on or accessible through this website is not a part of this proxy statement, and the inclusion of such website address in this proxy statement is an inactive textual reference only. Any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website to the extent required by applicable rules and exchange requirements.

Item 11. Executive Compensation

The information required to be furnished pursuant to this Item will be set forth in our proxy statement for the 2023 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2022, and is incorporated herein by reference.

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

The information required to be furnished pursuant to this Item will be set forth in our proxy statement for the 2023 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2022, and is incorporated herein by reference.

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

The information required to be furnished pursuant to this Item will be set forth in our proxy statement for the 2023 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2022, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required to be furnished pursuant to this Item will be set forth in our proxy statement for the 2023 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2022, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

1. ***Consolidated Financial Statements***: The following Consolidated Financial Statements and Supplementary Data and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:
    - Consolidated Balance Sheets at December 31, 2022 and 2021

- Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2022 and 2021
- Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021
- Notes to Consolidated Financial Statements

2. ***Exhibits***: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1/A filed September 25, 2019).
3.2	Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.3	Certificate of Correction to Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 22, 2019 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.4	Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective December 24, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 30, 2019).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated November 23, 2020 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 24, 2020).
3.6	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).
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 11, 2019).
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series E-1 Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed August 16, 2019).
4.3	Form of Series E Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed July 11, 2019).
4.4	Form of Series E-1 Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 16, 2019).
4.5	Warrant to Purchase Shares, dated August 6, 2021, issued by the Company to Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 11, 2021).
4.6	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.7 to the Company's Amendment No. 1 to the Registration Statement on Form S-1 filed February 7, 2020).
4.7	Form of Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC, including the form of Series F warrant (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-1/A filed on April 20, 2020).
4.8**	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed July 20, 2022)
4.9	Form of Registration Rights Agreement dated July 18, 2022 between the Company and each other party a signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 20, 2022)
4.10	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 13, 2022)

Exhibit No.	Description
4.11	Form of Registration Rights Agreement dated December 7, 2022 between the Company and each other party a signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 13, 2022)
4.12**	Description of Securities
10.1	Delcath Systems, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 4.01 to the Company's Current Report on Form 8-K filed on February 7, 2019). #
10.2	Delcath Systems, Inc. 2020 Omnibus Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021 filed on August 10, 2021). #
10.3	Employment Agreement dated August 31, 2020, between the Company and Gerard Michel. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 1, 2020).
10.4	Inducement Award Stock Option Award Agreement dated October 1, 2020, between the Company and Gerard Michel. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 1, 2020). #
10.5	Employee Confidentiality, Invention Assignment and Restrictive Covenants Agreement, dated August 31, 2020, between the Company and Gerard Michel (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 1, 2020). #
10.6	Executive Security Agreement between the Company and John Purpura (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on March 26, 2018). #
10.7	Form of Employee Confidentiality and Restrictive Covenant Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 26, 2011). #
10.8	Form of Indemnification Agreement dated April 8, 2009 between the Company and members of the Company's Board of Directors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 10, 2009).
10.9	Lease dated August 2, 2011 between MBP Co-Ownership Group and Delcath Systems Limited (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 filed on November 9, 2011).
10.10	Second Amendment to Sublease, dated September 22, 2020, between the Company and Kasowitz Benson Torres LLP. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020 filed on November 12, 2020).
10.11	Controlled Equity Offering SM Sales Agreement, dated August 18, 2020, between the Company and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed on August 18, 2020).
10.12	Loan and Security Agreement, dated August 6, 2021, between Delcath Systems Inc. as borrow and Avenue Venture Opportunities Fund, L.P., as lender (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 11, 2021).
10.13	Supplement to the Loan and Security Agreement, dated August 6, 2021, between the Company as borrower and Avenue Venture Opportunities Fund, L.P., as lender (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 11, 2021).
10.14	Second Note Amending Agreement, dated August 6, 2021, between the Company and Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed August 11, 2021).

Exhibit No.	Description
10.15	Note Amending Agreement, dated as of July 15, 2019, between the Company and Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed August 11, 2021).
10.16	8% Secured Promissory Note, dated July 15, 2019, issued by the Company to Rosalind Opportunities Fund I L.P. (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed August 11, 2021).
10.17	8% Secured Promissory Note, dated July 15, 2019, issued by the Company to Rosalind Master Fund L.P. (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed August 11, 2021).
10.18	Securities Purchase Agreement dated July 18, 2022, between the Company and the signatories thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 20, 2022)
10.19	Securities Purchase Agreement dated December 7, 2022, between the Company and the signatories thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 13, 2022)
21**	Subsidiaries of the Company
23.1**	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on signature page hereto)
31.1**	Certification by Principal Executive Officer Pursuant to Rule 13a 14.
31.2**	Certification by Principal Financial Officer Pursuant to Rule 13a 14.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101

\# Indicates management contract or compensatory plan or arrangement.
* Furnished herewith.
** Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DELCATH SYSTEMS, INC.

/s/ Gerard Michel

Gerard Michel
Chief Executive Officer
(Principal Executive Officer)
Dated: March 27, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of the undersigned constitutes and appoints Gerard Michel as attorney-in-fact and agent, with full power of substitution and re-substitution, for and in the name, place and stead of the undersigned, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gerard Michel Gerard Michel	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2023
/s/ Anthony Dias Anthony Dias	Principal Financial Officer	March 27, 2023
/s/ John R. Sylvester John R. Sylvester	Chairman of the Board	March 27, 2023
/s/ Elizabeth Czerepak Elizabeth Czerepak	Director	March 27, 2023
/s/ Steven Salamon Steven Salamon	Director	March 27, 2023
/s/ Roger G. Stoll, Ph D Roger G. Stoll, Ph D	Director	March 27, 2023
/s/ Gil Aharon Gil Aharon	Director	March 27, 2023