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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, 2023

☐ **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.)**
566 Queensbury Avenue, Queensbury, NY	**12804**
(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 ☒

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 $5.83 per share, as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter was $81,667,153.

On March 18, 2024, the registrant had outstanding 24,562,692 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2024 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, 2023. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K for the period ended December 31, 2023, 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, 2023 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, 2023 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, future revenue and our need for additional financing;
- the commencement of future clinical trials, if any, and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT, HEPZATO, and future products, if any, generate revenue and successfully obtain reimbursement for the products and/or the associated procedures;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of CHEMOSAT, HEPZATO, and future products, if any;
- the rate and degree of market acceptance and clinical utility of CHEMOSAT, HEPZATO, and future products, if any;
- developments relating to our competitors and our industry;
- the initiation and success of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source components of CHEMOSAT, HEPZATO, and future products, if any, and enter into supplier contracts;
- our ability to source melphalan for use in HEPZATO;
- 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 ™ 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 on 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, or conduct future product development, including clinical trials, if any.
- If we are not in compliance with the terms and conditions of our existing debt agreement, our business and financial condition may be adversely affected.
- We have incurred significant losses since inception, expect to incur significant and increasing losses for at least this year, and continuing losses may exhaust our capital resources. We may not generate significant revenue for the foreseeable future.
- We have only recently obtained regulatory approval for HEPZATO in the United States and commenced the commercial launch of HEPZATO. We have limited experience as a commercial company and generating revenue from product sales. If the commercial launch of HEPZATO is unsuccessful or any future approved products are unsuccessful, we may never be profitable.
- 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 must maintain or enter into acceptable arrangements for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT and we may not be able to ensure adequate supply impacting our ability to successfully commercialize HEPZATO in the United States and CHEMOSAT in the EU 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.
- We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and HEPZATO.
- We may be unsuccessful in commercializing CHEMOSAT and HEPZATO because of inadequate infrastructure or an ineffective commercialization strategy.
- The development and approval process in the United States and abroad could take many years, require substantial resources and may never lead to the approval of our product candidates by the FDA for use in the United States or by foreign regulators in their respective jurisdictions.
- Our ability to market HEPZATO is limited to those uses that are approved.
- If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications.
- 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/UK will be significantly limited.
- We relied and may continue to rely on third parties to conduct certain elements of our clinical trials for CHEMOSAT and HEPZATO, should we seek to obtain regulatory approval for use of these products to treat additional indications for which we do not currently have regulatory approval, or for any future product candidates, if any, and if these third parties do not perform their obligations to us, we may not be able to obtain the necessary regulatory approvals for our products or product candidates, as applicable.
- 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.
- 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 healthcare 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.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to information privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.
- Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may have a material adverse effect on us.
- Consolidation in the healthcare industry could lead to demands for price concessions.
- Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.
- We have not and may not be able to adequately protect our intellectual property rights throughout the world.
- 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 market price of our common stock has been volatile, and may continue to fluctuate significantly, which could result in substantial losses for investors.
- Because of volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.
- 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.
- The loss of key personnel could adversely affect our business.

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 566 Queensbury Avenue, Queensbury, New York 12804. 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 cancers metastatic to the liver. Our lead product, the HEPZATO™ KIT ("HEPZATO" melphalan for Injection/Hepatic Delivery System), a drug/device combination product, was approved by the US Food and Drug Administration (the "FDA") on August 14, 2023, indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection, or radiation. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as 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 in the liver. The first commercial use of HEPZATO for the treatment of metastatic hepatic dominant uveal melanoma ("mUM") took place in January 2024.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by 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 us 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).

We have sufficient raw material and component constituent parts of HEPZATO KIT to meet the first year of our anticipated demand and we intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation (EU) 2017/745, 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.

Clinical Development Program

Our clinical development program for HEPZATO was comprised of the FOCUS Clinical Trial for Patients with metastatic hepatic dominant Uveal Melanoma (the "FOCUS Trial"), a global registration clinical trial that investigated objective response rate in patients with mUM. The current focus of our clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in patients with mUM, either as monotherapy or in combination with immunotherapy. We expect that this data will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support reimbursement in various jurisdictions, including the United States.

In addition to HEPZATO's use to treat mUM, we believe that HEPZATO has the potential to treat other cancers in the liver, such as metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic breast cancer and intrahepatic cholangiocarcinoma, and plan to begin one or more studies of HEPZATO KIT to treat such conditions in 2024. We believe that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

Cancers in the Liver—A Significant Unmet Medical 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 in the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers in the liver consist of primary liver cancer and cancers metastatic to the liver. Primary liver cancers (hepatocellular carcinoma, or HCC, and Intrahepatic Cholangiocarcinoma or ICC) originates in the liver or biliary tract 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. Cancers metastatic to the liver, also called liver metastasis, or secondary liver cancer, result 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 or successfully treated. 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. The estimated total potentially addressable market for liver cancer (primary and metastatic) is approximately 200,000 in the United States per year. It is estimated the total addressable market in the United States for mUM, ICC, HCC breast cancer, neuroendocrine, pancreatic, and colorectal, is well over $1.0 billion.

Treatment of liver cancer is difficult. Current liver cancer treatment options include surgery, systemic treatment with anticancer drugs, and liver directed treatment options. Surgery options include surgical resection, liver transplant, and isolated hepatic perfusion ("IHP"). While surgical resection and liver transplant, when feasible, offer best possible outcomes for liver cancer patients, the percentage of patients that qualify for these procedures is low, generally 10% or less of the total liver cancer population. Clinical efficacy observed with IHP provided the rationale for using percutaneous hepatic profusion ("PHP") in mUM, as well as other tumor types, including colorectal cancer. Systemic options include systemic chemotherapy and immunotherapy agents. Minimally invasive options include external beam radiation therapy and liver directed procedures.

Procedures in the liver, and liver directed treatments (interventional oncology) are performed by an interventional radiologist. These procedures include trans-arterial chemoembolization (TACE, DEBTACE) and Radioembolization (SIRT, TARE, or Y90). TACE is used in approximately 50,000 to 60,000 treatments per year and Y90 is used in 10,000 to 15,000 treatments per year. We believe that CHEMOSAT and HEPZATO represent an important advancement in the potential liver-directed treatment of primary liver cancer and other cancers metastatic to the liver. Two key factors differentiate PHP with HEPZATO KIT and CHEMOSAT from other liver directed therapies; the ability to treat the entire liver, including radiologically invisible micrometastases, and the repeatability of the procedure. We believe PHP with HEPZATO KIT and CHEMOSAT is uniquely positioned either as a standalone therapy or as a complement to other therapies. In clinical studies with HEPZATO KIT and CHEMOSAT, both treatment-naive and pretreated patients have benefited from the treatment, thus expanding the use to multiple lines of treatment.

Uveal Melanoma

Uveal melanoma frequently metastasizes to the liver. Based on third party research that we commissioned approximately 5,000-6,200 cases of uveal melanoma are diagnosed in the United States and Europe annually, and approximately 50% of these patients will develop metastatic disease. Of metastatic cases of uveal melanoma, approximately 90% of patients develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once uveal 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 uveal melanoma liver metastases. Based on our research, an estimated 800 patients with uveal melanoma liver metastases in the United States, and 1,200 patients in Europe may be eligible for treatment with HEPZATO KIT or CHEMOSAT annually. Currently 55% of the patients are not eligible for KIMMTRAK, the only approved uveal melanoma systemic therapy, and most 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 $600 million per year.

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. We estimate approximately 98,000

CRC patients in the United States, the United Kingdom and the European Union annually could be candidates for treatment with HEPZATO (if it received FDA approval for such treatment) 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 that there are, annually, 726,259 women diagnosed with breast cancer in the United States, the European Union 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 involvement in the United States and the European Union could be candidates for treatment with HEPZATO KIT and CHEMOSAT. An additional 10,000 patients could benefit from treatment with HEPZATO (if it received FDA approval for such treatment) 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 from 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 (if it received FDA approval for such treatment) and CHEMOSAT.

Pancreatic Cancer

Pancreatic adenocarcinoma has a poor prognosis. 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 affects 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 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 new pancreatic cancer patients each year in the United States and European Union with hepatic only involvement. Given the rapid progression of the disease and rapid decline in the overall patient status it is unknown at this time the estimated number of candidates for treatment with HEPZATO KIT (if it received FDA approval for such treatment) and CHEMOSAT.

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 local treatments. According to third party research that we commissioned, we estimate that approximately 2,000 ICC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with HEPZATO KIT (if it received FDA approval for such treatment) and CHEMOSAT.

About HEPZATO KIT and CHEMOSAT

HEPZATO KIT is a drug/device combination product designed to administer high-dose chemotherapy directly into the liver while limiting 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 PHP procedure, two 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 melphalan from the blood before the filtered blood is returned to the patient's circulatory system thereby reducing systemic exposure to the drug and related 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 KIT is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical trial settings were permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. HEPZATO KIT received regulatory approval by the FDA in August 2023 for adult uveal melanoma patients with unresectable liver metastases only, and patients with unresectable liver metastases and extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissue or lung that is amenable to resection or radiation. HEPZATO KIT's indication is not limited to specific HLA phenotypes or to a specific line of treatment. The HEPZATO KIT consists of the medical device constituent part and the drug melphalan hydrochloride for injection. Whereas, CHEMOSAT is the medical device-only configuration that is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party secured by practitioners.

The FOCUS Trial

The FOCUS Trial evaluated the safety and efficacy of treatment with the HEPZATO KIT for patients with mUM. The primary endpoint of overall response rate (ORR) was assessed by an Independent Review Committee per RECIST v1.1. The primary endpoint of the trial, ORR was met with a wide margin and the safety profile was acceptable. Results from the FOCUS Trial were reviewed by the FDA and were the basis for approval of HEPZATO KIT on August 14, 2023. Detailed results from the FOCUS Trial are submitted for publication and will be presented at upcoming scientific meetings.

CHOPIN Trial

The Leiden University Medical Center completed the Phase 1b portion of a Phase 1b/2 trial (CHOPIN trial) on the use of 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 evaluate the safety and efficacy of systemic ICI therapy with ipilimumab plus nivolumab (IPI+NIVO) when combined with Delcath's liver-targeted percutaneous hepatic perfusion treatment in metastatic uveal melanoma patients. Published results from the Phase 1b portion of the trial include updated safety and efficacy results which were 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 cycles of PHP (melphalan 3mg/kg, max 220 mg per cycle) combined with four cycles of IPI+NIVO, escalating the dosing from 1mg/kg each IPI+NIVO (cohort 1) to IPI 1mg/kg + NIVO 3mg/kg (cohort 2). In the seven patients, best tumor responses 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 Progression Free Survival (PFS) was 29.1 months (95% CI 11.9 – 46.3) and the median Duration Of Response (DOR) was 27.1 months (range 7.4 – 28.5). At the time of the cut-off date all patients were still alive and three of four patients who subsequently experienced progressive disease continued with treatment in the form of repeated PHP cycles.

The ongoing randomized phase 2 part of the CHOPIN trial comparing PHP alone with PHP plus IPI/NIVO, which will include another 76 patients (38 per arm), is expected to complete patient enrollment by end of 2024. Presentation of Phase 2 results of the CHOPIN trial is expected in 2025.

Market Access and Commercial Clinical Adoption

United States

The first commercial use of HEPZATO KIT for the treatment of mUM occurred in January 2024. We are working with numerous leading cancer centers across the United States which have indicated interest in HEPZATO to treat patients and provide access to the treatment for patients nationwide. HEPZATO is available for cancer centers to treat patients upon completion of required training as documented in our Risk Evaluation and Mitigation Strategy ("REMS"). REMS focuses on preventing, monitoring, and/or managing specific risks associated with a product.

Our field team is comprised of liver directed therapy managers, clinical specialist representatives, oncology area managers and medical science liaisons who work directly with the cancer centers to obtain the required training. In conjunction with the first commercial treatment, we also launched websites relating to the HEPZATO KIT, including www.HEPZATOKIT.com, www.HEPZATOKITREMS.com, and www.HEPZATOKITACCESS.com, to support the commercial launch. On www.HEPZATOKIT.com, we have a healthcare setting locator which identifies certified healthcare facilities that have expressed an interest in performing the HEPZATO KIT procedure and given us permission to list its facility. In addition, www.HEPZATOKITREMS.com contains a healthcare setting locator that lists facilities that have completed and filed all documentation required under REMS.

Upon activation of the cancer center, the center is able to commercially treat patients with HEPZATO. We have identified over 30 cancer centers with the potential to treat mUM patients, however, there is no guarantee that we ever offer HEPZATO to any of these sites.

U.S. Reimbursement

Usage of HEPZATO by the cancer centers will depend on the availability of coverage and reimbursement from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. For products administered under the supervision of a physician, particularly in a hospital setting, the ability of a treating facility to obtain adequate reimbursement can be challenging and dependent on the type of health insurance a patient is covered and the treating facility's agreement (or lack of agreement) with such insurance. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Furthermore, the classification, as either outpatient or inpatient, of the treatment procedure associated with the administering of a product will impact a treating facility's reimbursement. Many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform, or a predetermined rate for all hospital inpatient care provided as payment in full. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to HEPZATO.

The Company expects that payors will follow decisions made by the Centers for Medicare and Medicaid Services ("CMS"), as the administrator for the Medicare program, regarding HEPATO reimbursement. A facility at which HEPZATO is used will seek reimbursement for the cost of the HEPZATO and the attendant procedure.

Even if a cancer center obtains 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, 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.

For many third party payors, the Company expects that each patient candidate for treatment with HEPZATO will likely have to go through a medical pre-authorization process, which may require the Company to provide 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. The coverage determination process may require providing scientific and clinical support for the use of our products to each payor separately. As such, in order to assess available benefits and coordinate the treatment pathway before a patient is treated with HEPZATO, the Company has engaged a third-party benefits coordinator to guide the patient and a treating healthcare provider through the pre-authorization and reimbursement process.

On January 30, 2024, CMS announced an established permanent and product-specific J-Code for HEPTAZO KIT. The J-Code (J9248) will become effective on April 1, 2024. We expect that, beginning on April 1, 2024, treating facilities will utilize J9248 when billing for the outpatient use of HEPZATO.

Although private third-party payors often use CMS as a model for their coverage and reimbursement decisions, they also have their own methods and approval process apart from CMS's determinations. Therefore, even if the cancer center obtains 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.

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.

Europe

Since the launch of CHEMOSAT in Europe, there have been over 1,475 commercial treatments and CHEMOSAT is currently available in over 23 European cancer centers in 7 European countries. 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, breast, and pancreatic cancer, as well as neuroendocrine tumors.

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. On March 1, 2022, we assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe. UK Interventional Procedures Advisory Committee (IPAC) upgraded the recommendation from "Research Only" to "Special".

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.

On February 28, 2022, CHEMOSAT received Medical Device Regulation certification under the European Medical Devices Regulation (EU) 2017/745, 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 uveal melanoma (mUM). 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, allowing more hospitals to secure funding to utilize CHEMOSAT. This increased level of evidence will ultimately support securing full funding for the treatment under DRG codes and other mechanisms.

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 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.

U.S. Regulatory Environment

In the United States, the FDA regulates drug and device products under the Food, Drug and Cosmetic Act (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. 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 had 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 Investigational New Drug (IND) application, 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 the FDA will approve any of our product candidates 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 U.S.' 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.

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 Complete Response Letter, or CRL, if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing.

Approval may be contingent on the implementation and adherence to a Risk Evaluation and Mitigation Strategy, or REMS, that focuses on preventing, monitoring, and/or managing specific risks associated with a 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.

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.

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 approval 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. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, any product modifications 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.

U.S. Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws apply to certain business practices in the biopharmaceutical industry. 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 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 payors 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.

In addition to the aforementioned federal fraud and abuse laws, the majority of states also have statutes or regulations similar to these 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.

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 states the authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and to 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.

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." Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA are 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 (and the maximum prices as a result of the negotiations becoming effective beginning on January 1, 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D for 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, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Orphan drugs, even if covered by Part B or Part D, are not subject to the IRA's provisions regarding direct price negotiation, although the exemption arguably only applies to orphan drugs with a single approved indication. Therefore, it is currently unclear about the potential long-term impact on the pricing of orphan drugs' with planned follow-on or supplemental indications.

On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. 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 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. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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.

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 EU Medical Device Regulation became effective on May 25, 2017, and governs all facets of medical devices. 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 (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 entailed 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 twelve U.S. utility patents, one U.S. design patent, three pending U.S. utility patent applications, nine 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), four issued foreign counterpart design patents, and one pending foreign counterpart patent application. Patents to our chemotherapy filtration apparatus "Apparatus for Removing Chemotherapy Compounds from Blood", including claims directed to apparatus, methods, kits, and filter media, were issued by the U.S. Patent and Trademark Office (USPTO) in July 2017, October 2018, August 2019, February 2020, February 2022, and April 2023. 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. The patent issued in April 2023 has claims directed to a percutaneous hepatic perfusion procedure and our filter media. Patents directed to our Filter and Frame Apparatus "Filter and Frame Apparatus and Method of Use" were issued by the USPTO in April 2016, February 2021, August 2021, and December 2023. In April 2016 and August 2021 patents were issued by the USPTO with claims directed to our filter and frame apparatus. In February 2019, a patent was issued by the

USPTO with claims directed to a method of using our filter and frame apparatus and in December 2023, a patent was issued by the USPTO with kit claims that comprise our filter and frame apparatus and that are directed to delivering a chemotherapeutic agent to the liver of a patient. These claims are directed to HEPZATO® KIT. A Hong Kong patent directed to our Filter and Frame Apparatus was issued in March 2018. A Hong Kong patent directed to our chemotherapy filtration apparatus was issued in September 2023. European patents were granted by the European Patent Office for our chemotherapy filtration apparatus in December 2018 and 2023 and in July 2019 a European patent was granted by the European Patent Office with claims to a kit of parts comprising our chemotherapy filtration apparatus and 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 April 2017 and August 2019, European patents were granted by the European Patent Office with claims directed to our filter and frame apparatus, the August 2019 patent was validated in eleven countries to provide additional European patent coverage for our filter and frame apparatus to the European patent directed to the filter and frame apparatus that was granted in April 2017. In March 2022, a European patent was granted by the European Patent Office and validated in eight countries with kit claims comprising our filter and frame apparatus and directed to CHEMOSAT®. 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.

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, U.S. patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. In October 2023, after receiving FDA approval for the HEPZATO KIT, we requested an extension of the term for one of our patents. 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.

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 and HEPZATO 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 mUM. HLA-A *02:01 patients represent approximately 45% of patients with uveal melanoma. HEPZATO is approved to treat all mUM patients and is the only approved drug to treat the remaining 55% of patients. Traditionally, mUM patients have been treated with both systemic and a variety of local regional techniques. There are numerous companies developing and marketing devices for the performance of local regional procedures, 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. These procedures include trans-arterial chemoembolization (TACE, DEBTACE) and Radioembolization (SIRT, TARE, or Y90). Neither of these procedures are approved for the treatment of mUM.

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 double balloon catheter 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 most of the components of CHEMOSAT and HEPZATO. CHEMOSAT and HEPZATO and their components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution, and we use third-party vendors to perform the sterilization process.

We are required to comply with cGMP regulations and quality system regulations relating to our manufacturing of HEPZATO KIT for distribution in the United States. We are also 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 also consists of individuals with significant experience in the pharmaceutical and biotechnology industries. As of March 1, 2024, including our management team, we had approximately 76 full time employees, of which 66 are located in the United States and 10 are located in Europe. On March 18, 2024, we appointed Martha S. Rook, Ph.D., as Chief Operating Officer. We intend to hire additional employees as needed 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 those related to marketing, quality assurance, manufacturing, 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. We provide our employees base salaries and leave and benefits programs that we believe are competitive and consistent with industry standards. 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 to define our expectations regarding 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, depending on their role, with the option to work from home. We have consolidated our offices to Queensbury, New York, but many of our employees work remotely outside of the Queensbury, New York area.

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.

Item 1A. Risk Factors

An investment in our securities involves 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.

Our independent registered public accounting firm issued a report dated March 26, 2024 in connection with the audit of our financial statements as of December 31, 2023, 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, 2023, 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 was dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient capital or otherwise when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. 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, or conduct future product development, including clinical trials, if any.

Developing and commercializing pharmaceutical products, including conducting preclinical testing and clinical trials and preparing for and commencing commercial launch are long, expensive, and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development, including following commercial launch.

Our expenses will increase, particularly as we commercialize HEPZATO in the United States, including expenses related to product sales, marketing, manufacturing and distribution. If we are not able to generate significant revenue from either or both of HEPZATO and CHEMOSAT, we will require additional substantial financing to further commercialize our products in the United States and the European Union and any other jurisdictions where we may receive regulatory approval for our products, and in order to conduct future product development, if any, including clinical trials for new product candidates or for HEPZATO or CHEMOSAT in additional indications for which we do not currently have regulatory approval. In the absence of potential proceeds from cash exercises of currently outstanding warrants and convertible notes and/or significant revenue from either or both of HEPZATO and CHEMOSAT, we may require substantial additional funding to continue the launch and commercialization of HEPZATO in the U.S., complete product development projects or clinical trials. If we are unable to raise additional capital or generate significant revenue from either or both of HEPZATO and CHEMOSAT, our ability to complete product development projects or clinical trials, including trials for HEPZATO and CHEMOSAT, in additional indications, may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. If we are not successful in generating product revenue, 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 or contractual obligations, such as restrictive covenants that are sometimes included in debt financing.

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

- our ability to successfully sell HEPZATO in the United States and CHEMOSAT in Europe;
- the outcome of any of our future clinical studies;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- our ability to secure the continuous supply of melphalan and other critical components of HEPZATO and CHEMOSAT from facilities in compliance with applicable manufacturing regulations;
- our ability to secure commercially reasonable terms for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT;
- the timing, costs and regulatory approval processes associated with developing our and/or our partners' manufacturing operations;
- the cost and ability to effectively establish and maintain the commercial infrastructure and manufacturing capabilities required to support the commercialization of HEPZATO, CHEMOSAT and any other products for which we receive marketing approval including product sales, medical affairs, marketing, manufacturing and distribution;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- executive compensation, including the cost of attracting senior executives;

- our headcount growth and associated costs as we expand our research and development and further establish a commercial infrastructure;
- our debt requirements, including contractual obligations under such agreements;
- 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 in compliance with the terms and conditions of our existing debt agreement, our business and financial condition may be adversely affected.

On August 6, 2021, we entered into the Loan and Security Agreement with Avenue Venture Opportunities Fund, L.P., as amended on March 31, 2023 (the "Avenue Loan Agreement"). The Avenue Loan Agreement provides for a term loan in an aggregate principal amount of up to $20.0 million, pursuant to which, we have borrowed $15 million. 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. On March 31, 2023, we reached an agreement to amend the Avenue Loan Agreement to allow us to make interest only payments until September 30, 2023, with an additional extension option upon FDA approval for the HEPZATO KIT and subsequent receipt of $10 million from the sale and issuance of equity securities. After the additional extension requirements were met, we elected to extend the interest only payment period to December 31, 2023 and principal payments began in January 2024.

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 pursuant to the Avenue Loan Agreement on December 31, 2023 was 16.20%. The Avenue Loan Agreement is secured by all of our 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.

If we do not make our required monthly repayments beginning on January 1, 2024, in accordance with the March 2023 amendment to the Avenue Loan Agreement, we would be in default of 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.

Raising additional capital, or the exercise or conversion of securities exercisable or convertible into shares of common stock, may cause dilution to our existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us 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, exercise of our outstanding warrants and conversion of outstanding preferred stock, strategic alliances and license and development agreements in connection with any collaborations. 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.

We have incurred significant losses since inception, expect to incur significant and increasing losses for at least this year, and continuing losses may exhaust our capital resources.

As of December 31, 2023, we had $12.7 million in cash and cash equivalents and $19.8 million in short-term investments. 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, 2023, and 2022, we incurred net losses of approximately $47.7 million and $36.5 million, respectively, and expect to continue to incur losses in 2024. To date, we have funded operations through a combination of private placements and public offerings of our securities and 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 further commercialize our products in the United States and the European Union and any other jurisdictions where we may receive regulatory approval for our products or conduct future product development, if any, including clinical trials for new product candidates or for HEPZATO or CHEMOSAT in additional indications for which we do not currently have regulatory approval.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our ability to generate any product revenue from HEPZATO and CHEMOSAT or future product candidates, if any, also depends on a number of additional factors, including our ability to:

- successfully commercialize and sell HEPZATO in the United States pursuant to our existing FDA approval;
- successfully complete research and clinical development of future product candidates, if any, including clinical trials for new product candidates or for HEPZATO or CHEMOSAT in additional indications for which we do not currently have regulatory approval, and obtain regulatory approval for those product candidates and indications, as applicable;
- establish and maintain supply and manufacturing relationships, under commercially reasonable terms, with third parties, and ensure adequate, scaled up and legally compliant manufacturing of necessary components, including melphalan, bulk drug substances and drug products to maintain sufficient supply;
- launch and commercialize any product candidates for which FDA approval is obtained;
- 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 significant 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.

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 product, 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 product 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 result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell our products, 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 insurance, it may be insufficient to cover one or more large claims.

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

We have only recently obtained regulatory approval for HEPZATO in the United States and commenced the commercial launch of HEPZATO. We have limited experience as a commercial company and generating revenue from product sales. If the commercial launch of HEPZATO is unsuccessful or any future approved products are unsuccessful, we may never be profitable.

We received approval by the FDA for HEPZATO in the United States in August 2023 and began generating revenue from product sales during the first quarter of 2024. Our ability to become and remain profitable is heavily dependent on our ability to generate revenue from HEPZATO for the treatment of mUM. The success of our commercialization will depend on a number of factors, including, among others, the continued development of our commercial organization, including our internal sales and marketing team and distribution capabilities, our ability to navigate the significant expenses and risks involved with the development and management of such capabilities, satisfying any post-marketing regulatory requirements, our ability to secure adequate healthcare coverage and the acceptance of HEPZATO by patients and third-party payors. If HEPZATO, or any other future approved product, does not achieve an adequate level of acceptance, coverage, pricing or reimbursement, we may not generate significant revenue from product sales and we may not be profitable. Even if we successfully commercialize HEPZATO in the United States, we may be unable to achieve or maintain profitability, unless HEPZATO is approved in other jurisdictions or for additional indications. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues from product sales of HEPZATO, or any future approved products, or if or when we might achieve profitability.

If we are unsuccessful in accomplishing our objectives, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize HEPZATO or any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We must maintain or enter into acceptable arrangements for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT and we may not be able to ensure adequate supply impacting our ability to successfully commercialize HEPZATO in the United States and CHEMOSAT in the EU or complete any future clinical trials.

Each manufacturer/supplier of components for the production of HEPZATO and CHEMOSAT must be in compliance with cGMPs. Our supply of critical components of HEPZATO and CHEMOSAT includes the use of one contracted supplier. In order to successfully commercialize HEPZATO, we also must be able to enter into long-term supply agreements for critical components, including melphalan, under commercially reasonable terms.

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 in 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.

FDA inspections of our suppliers/manufacturers, even for products other than those supplied to us, may result in the supplier/manufacturer being shut down or unable to deliver critical components to us in a timely manner. Such risks are increased for those components for which we have one contractual supplier.

We currently have an agreement with one supplier of melphalan and, with the goal of minimizing the risk of a supply interruption, are in discussions with several melphalan ANDA holders who have indicated interest in supplying melphalan to us. We are aware that in 2023, the FDA issued our current melphalan manufacturer 483 observations as a result of an inspection unrelated to the HEPZATO and the manufacturer is working to address these observations.

Although we are pursuing a variety of strategies to mitigate the risk of a supply interruption of commercial supply for our product, we cannot assure you that such shutdown and related matters will not result in a loss of supply in the event the shutdown is longer than anticipated or in the event regulatory action is taken against the supplier. In any such situation, this could have a material adverse impact on our business, operations and financial condition.

We may pursue agreements with additional contract manufacturers to produce melphalan and other critical components for use in any future clinical trial programs and for the production of CHEMOSAT and HEPZATO, as well as for labeling and finishing services. We may not be able to enter into such arrangements on commercially reasonable terms or at all. 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 for CHEMOSAT 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 for other indications 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 product, 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 additional clinical trials required to obtain regulatory approval and commercialize our product for other indications.

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 ("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 we are not aware of any direct impacts of the war between the Ukraine and the Russian Federation, the conflicts in the Middle East, or any other global conflict on our supply chain, such current or future conflicts could adversely impact our ability to obtain components and/or significantly increase the cost of obtaining such components for our products from third-party suppliers in a timely manner or at all.

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 adversely impacted. 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.

We may be unsuccessful in commercializing CHEMOSAT and HEPZATO because of inadequate infrastructure or an ineffective commercialization strategy.

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 may not succeed.

We may not be successful in our efforts to expand the commercialization of CHEMOSAT in the European Union or United Kingdom, 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. 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. If we are unsuccessful in accomplishing our objectives, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize HEPZATO or any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

If we are unable to establish, maintain and, if necessary, expand sales and marketing capabilities or enter into agreements with third parties to sell and market HEPZATO in the United States or other product candidates, we may not be successful in commercializing HEPZATO in the United States or any other of our product candidates if they are approved.

We have limited experience in the sale, marketing and distribution of pharmaceutical products in the United States. To achieve commercial success for HEPZATO and any other product candidates, if approved, for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. We have established sales and marketing capabilities to support our commercial launch of HEPZATO for the treatment of adult patients with unresectable hepatic-dominant metastatic uveal melanoma in the United States. We may need to further build our sales and marketing infrastructure, either directly or with third-party partners, to maintain our ongoing commercialization efforts and to commercialize HEPZATO in other indications or to commercialize any of our other product candidates for which we obtain marketing approval.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time

consuming. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize HEPZATO and other product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive or integrated product offerings; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of product revenue to us is likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing HEPZATO in the United States or any of our product candidates for which we obtain marketing approval.

We may use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO, but it 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 the United Kingdom. If we seek similar authorization or approvals in other foreign countries, 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.

We may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for the commercial success of CHEMOSAT or HEPZATO, in which case we may not 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. We may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for the commercial success of CHEMOSAT and HEPZATO. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. In addition, since CHEMOSAT currently is approved for commercialization solely in the EU and limited other jurisdictions (including the United Kingdom), and HEPZATO is approved only in the United States, if we are unsuccessful in commercializing the products in the EU and the United States, we will have no means of generating revenue.

In addition, the potential market opportunity for CHEMOSAT and HEPZATO is difficult to precisely estimate. Our estimates of the potential market opportunity for CHEMOSAT and HEPZATO for their approved indications, or in other indications include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. However, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for CHEMOSAT and HEPZATO could be smaller than our estimates of potential market opportunity. If the actual market for CHEMOSAT and HEPZATO is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

The sizes of the market opportunities for our product or product candidates, particularly HEPZATO for the treatment of mUM and CHEMOSAT for the treatment of cancers of the liver, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.

Our assessment of the potential market opportunity for HEPZATO and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal market research studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the

studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and our own studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research, we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for HEPZATO, CHEMOSAT or any of our other product candidates may be smaller than we expect, and as a result our revenue from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

Risks Related to FDA and Foreign Regulatory Approvals and Regulatory Matters

The development and approval process in the United States and abroad could take many years, require substantial resources and may never lead to the approval of our product candidates by the FDA for use in the United States or by foreign regulators in their respective jurisdictions.

We cannot commercialize, sell or market any products in the United States without prior FDA approval. Foreign regulatory authorities, such as the European Medicines Agency (the "EMA"), impose similar requirements. We have received regulatory approval for HEPZATO for the treatment of adult patients with unresectable hepatic-dominant mUM in the United States, but there is no assurance that we will receive regulatory approvals for HEPZATO for the treatment in other jurisdictions, or for other indications in any jurisdiction. Similarly, we have received approval for CHEMOSAT in Europe, but there is no assurance that we will receive regulatory approvals for CHEMOSAT in other jurisdictions. 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. Clinical development is a long, expensive and uncertain process and is subject to delays. 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. If we commence additional clinical trials in the future, we may encounter delays or rejections for various reasons.

If we do not maintain regulatory approval for HEPZATO, our business, results of operations, financial condition and prospects would be materially and adversely affected. In addition, our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

Our ability to market HEPZATO is 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. Our ability to market and promote HEPZATO is limited to the approved indication. 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 within their own medical judgment. 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. Thus, we may only market HEPZATO 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 to product, labeling or manufacturing processes or facilities, we may be required to submit and obtain prior FDA approval, which may require us to develop additional data or conduct additional studies. 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.

HEPZATO is now approved for the treatment of adult patients with unresectable hepatic-dominant metastatic uveal melanoma. The approval was based primarily on the results of the FOCUS Trial, a Phase 3, single arm, multicenter, open label study.

We plan to begin the study of HEPZATO for other indications in the future 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;
- we may not be able to establish and maintain the supply of necessary components, including melphalan, bulk drug substances and drug products to maintain sufficient supply to conduct such clinical studies;
- 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; and
- 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 product to market or require additional clinical trials;

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an 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.

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 in the EU. Since we may only promote the device within this specific indication, if physicians are unable or 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.

If physicians are unable or 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 unable or 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 the United States and will be in any other country where we receive marketing authorization or approval.

We are subject to ongoing regulatory obligations and oversight in the countries where HEPZATO and CHEMOSAT have been approved. 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. With HEPZATO's approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product are subject to extensive and ongoing regulatory requirements. In addition, post-marketing requirements for HEPZATO include implementation of a REMS program to ensure that the benefits of the product outweigh its risks. We must implement and ensure compliance with the HEPZATO REMS.

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:

- 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 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 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 or maintain 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 relied and may continue to rely on third parties to conduct certain elements of clinical trials for CHEMOSAT and HEPZATO, should we seek to obtain regulatory approval for use of these products to treat additional indications for which we do not currently have regulatory approval, or for any future product candidates, if any, and if these third parties do not perform their obligations to us, we may not be able to obtain the necessary regulatory approval for our products or product candidates, as applicable.

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 also plan on relying 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 intend to rely on third parties to conduct monitoring and data collection of our future clinical trials, however, we are ultimately 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 and we are dependent on third-party manufacturing and supply of critical components necessary for such clinical trial supply. To the extent a critical component relies on a single-sourced manufacture/supplier our ability to mitigate this risk decreases. Our failure, or any failure by such third-party partners, 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 product candidates then being studied.

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 Europe where we expect to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic-related group code ("ZE Code") which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where 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 payors 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. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We will seek reimbursement by third-party payors of the cost of HEPZATO, but there are no assurances that adequate third-party coverage will be adequate 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. 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.

In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. On January 30, 2024, CMS announced an established permanent and product-specific J-Code for HEPTAZO. The J-Code (J9248) will become effective on April 1, 2024. J-Codes are part of the Healthcare Common Procedure Coding System, or HCPCS, as maintained by CMS. However, there is no guarantee that these billing codes, or the payment amounts, if any, associated with such codes will not change in the future.

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

Our operations are 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 payors 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 on covered entities, their respective business associates and covered subcontractors, and others relating to the privacy, security and transmission of individually identifiable health information;
- Washington's My Health My Data Act, or MHMD, which broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws;
- 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 significant 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.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to information privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property and data.

Our data processing is subject to numerous domestic and foreign information privacy and security obligations such as various laws, regulations, guidance, industry standards, external and internal information privacy and security policies, contractual requirements, and other obligations relating to information privacy and security. 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 information privacy and security regulations, including but not limited to, HIPAA as amended by HITECH, which 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. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with federal and state healthcare laws and regulations.

Moreover, in the United States, federal, state, and local governments have enacted numerous information privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In the past few years, numerous U.S. states - including California, Virginia, Colorado, Connecticut, and Utah - have enacted comprehensive information privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern information privacy and security. For example, both the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") define personal data to include any information that relates to an identified or identifiable natural person with identifiable health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of their information. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, we may transfer personal data from Europe and other jurisdictions to the United States or other countries and may be subject to EU regulation with respect to limiting the cross-border transfers of such data out of the European Economic Area ("EEA") to the United States or other countries. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data

and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

We are also bound by contractual obligations related to information privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding information privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Furthermore, the legislative and regulatory landscape for information privacy and security continues to evolve, and there has been an increasing amount of focus on privacy and security 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. Obligations related to information privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions.

Compliance with information privacy and security laws may be time consuming, difficult and/or require us to devote significant resources. If we or the third parties on which we rely fail, or are perceived to have failed, to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to significant consequences including: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; reputational harm; or be forced to alter our business practices or change our business model. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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 (the "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 U.S. 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 (and the maximum price as a result of the negotiations becoming effective beginning on January 1, 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D for 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, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years

These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. 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. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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 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. The complexity and uncertainty of European patent laws have increased in recent years. In Europe, the new unitary patent system that came into effect in June of 2023, would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. 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 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 U.S. 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 U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

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

We rely on our trademarks as one means to distinguish for our customers our products from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion 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/ pharmaceutical 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 closing trading price of our common stock has varied between a high of $7.96 on May 31, 2023 and a low of $2.25 on November 14, 2023. 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 us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

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.

As of December 31, 2023, 22,761,554 shares of common stock are issued and outstanding, and we have reserved 20,510,737 shares of our common stock for future issuance pursuant to our stock option and equity incentive plans, outstanding warrants and preferred stock.

Future sales of a substantial number of shares of our common stock in the public market or the perception that such sales may occur, or the issuance of our common stock pursuant to outstanding warrants or convertible preferred stock, could cause immediate dilution and adversely affect the market price of our common stock. The sale or issuance of our common stock, as well as the existence of outstanding stock options and shares of common stock reserved for issuance under our equity incentive plans and outstanding warrants and convertible preferred stock, 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. 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 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. To date, we have designated the following series of 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), Series E-1 (12,960 shares), Series F-1 (24,900 shares), Series F-2 (24,900 shares), Series F-3 (34,860 shares) and Series F-4 (24,900 shares). 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 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. 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. For example, the terms of the Avenue Loan Agreement contain negative covenants prohibiting us from issuing cash dividends. 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.

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 our 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 and the third parties that support us 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, including by not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

We and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property and trade secrets (collectively, sensitive 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 variety of evolving threats, including cyber-attack, malicious intrusion, breakdown, destruction, loss of information privacy, or other significant disruption that threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by artificial intelligence (“AI”), and other similar threats. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Unremediated high risk or critical vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities.

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. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. 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 sensitive information, or otherwise compromise our confidential or proprietary information and disrupt our operations. Applicable information privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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, 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. 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 $700.0 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 not 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.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, global geopolitical conflicts, 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 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 the risk of government shutdowns reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, public health crises and ongoing global geopolitical conflict 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.

The 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. On August 1, 2023, Fitch Ratings downgraded the U.S.' long-term foreign currency issuer default rating to AA+ from AAA as a result of these repeated debt ceiling and budget deficit concerns. 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 United States 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.

Environmental, social and governance matters and any related reporting obligations may impact our business.

U.S. and international regulators, investors and other stakeholders are increasingly focused on environmental, social and governance matters. For example, new domestic and international laws and regulations relating to environmental, social and governance matters, including environmental sustainability and climate change, human capital management and cybersecurity, are under consideration or being adopted, which may include specific, target-driven disclosure requirements or obligations. Our response could require additional investments and implementation of new practices and reporting processes, all entailing additional compliance risk.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data results ("Information Systems and Data").

The Company's Senior Vice President of Finance ("SVPF") and Director of Information Technology ("IT") help identify, assess and manage cybersecurity risk, including input from employees, and devote resources to cybersecurity and risk management processes to adapt to the changing cybersecurity landscape and respond to emerging threats. The SVPF and Director of IT identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods including, for example maintaining manual and automated tools, conducting scans of threats and actors, evaluating threats reported to us, completing internal and external audits, and completing third-party threat assessments.

We have processes and standards to address cybersecurity matters and mitigate material cybersecurity risk. Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, encryption standards, access controls, disaster recovery/business continuity plans, incident detection and response, antivirus protection, remote access security, and multi factor authentication. All employees are required to complete cybersecurity trainings at least once a year.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our Director of IT along with management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the Board, which evaluates our overall enterprise risk.

The SVPF and Director of IT, who has over thirty years of experience in information technology and has both a computer science and information science degree, are responsible for developing and implementing our information security program and reporting on cybersecurity matters to the Board of Directors. We support our information security program with external resources including cybersecurity software providers and advisors as needed.

We have a vendor management processes to manage cybersecurity risks associated with our use of these external providers that includes a risk assessment for each vendor, reviews of vendor audits and reports, and we also impose certain contractual information security obligations on vendors. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider. Our assessment of risks associated with the use of third-party providers is part of our overall cybersecurity risk management framework.

The Board, as part of its general oversight function, participate in discussions with senior management and amongst themselves regarding cybersecurity risks. With the assistance of the Company's most senior IT manager, we review annually the cyber and data security risks of our overall IT environment. We assess cybersecurity risk and the overall environment which includes devices, IT systems, websites, social media accounts, manufacturing technology/systems and suppliers/vendors. The oversight from the Board includes material changes to policies, procedures, employee training and elements of the overall environment, as necessary, senior management provides an update on emerging cyber threats. The Board has access, as requested, to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of senior management, depending on the circumstances. Senior management works with the Company's cybersecurity incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's cybersecurity incident response plan includes reporting to the Board for certain cybersecurity incidents. We face a number of cybersecurity risks in connection with our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We and the third parties that support us 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, including by not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences" in Item 1A- Risk Factors.

Item 2. Properties.

Our corporate offices occupy 10,320 square feet at 566 Queensbury Avenue in Queensbury, New York. The corporate office is owned by the Company. We ended the sublease for our former corporate offices at 1633 Broadway, Suite 22C, New York, New York in February 2024. We also own a building comprised of approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York. These Queensbury 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 January 2024, we entered into a five-year lease for approximately 18,000 square feet of space at 2 Country Club 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.

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.

medac Matter

See Note 15 - "*Commitment and Contingencies - Litigation, Claims and Assessments - medac Matter*" for more information.

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.

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

Holders.

On February 29, 2024, there were approximately 57 holders of record of our common stock based on information furnished by Equiniti, LLC, the transfer agent for our securities.

Dividend Policy.
We have never declared or paid cash dividends on our common stock and have no intention to do so in the foreseeable future. Furthermore, the terms of the Avenue Loan Agreement contain negative covenants prohibiting us from issuing cash dividends.

Recent Sales of Unregistered Securities.

See Note 12 - "*Preferred Purchase Agreement*" for more information.

Repurchases of Equity Securities.

We did not repurchase any shares of our common stock during the fiscal year ended December 31, 2023.

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 cancers metastatic to the liver. Our lead product, the HEPZATO KIT ("HEPZATO" melphalan for Injection/Hepatic Delivery System), a drug/device combination product, was approved by the FDA on August 14, 2023 indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as 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 in the liver.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by 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 us 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).

Our clinical development program for HEPZATO was comprised of the FOCUS Trial, a global registration clinical trial that investigated objective response rate in patients with mUM. We are currently reviewing the incidence, unmet medical need, and development requirements for a broad set of cancers of the liver in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO KIT. In addition to HEPZATO's use to treat mUM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic breast cancer and intrahepatic cholangiocarcinoma, and plan to begin the study of

HEPZATO KIT to treat such conditions in the near future. We believe that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

We have sufficient raw material and component constituent parts of HEPZATO KIT to meet the first year of our anticipated demand and we intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation (EU) 2017/745, 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

On December 31, 2023, we had cash, cash equivalents and restricted cash totaling $12.7 million and short-term investments totaling $19.8 million, as compared to cash, cash equivalents and restricted cash totaling $11.8 million on December 31, 2022. During the years ended December 31, 2023 and 2022, we used $31.3 million and $25.0 million, respectively, of cash in our operating activities, and $6.3 million and $0.7 million, respectively, for principal payments of outstanding debt.

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 or maintain profitability. We have historically funded our operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of common stock and from the exercise of such warrants, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

Funding Requirements

If there is a substantial delay in the activation of sites approved to administer HEPZATO, we expect to need to raise additional capital under structures available to us, including debt and/or equity offerings, which may not be on terms favorable to us. In a substantially delayed site activation scenario, we will not have sufficient funds to meet our obligations within twelve months from the issuance date of these condensed consolidated financial statements. 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.

Debt financing and 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 or declaring dividends. If we raise funds through collaborations, or other similar 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 and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

We also expect to use cash and cash equivalents to fund activities relating to commercial support for HEPZATO, CHEMOSAT and any future clinical research trials and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including our ability to successfully commercialize HEPZATO and CHEMOSAT; the cost of and our ability to obtain additional regulatory approvals for HEPZATO and CHEMOSAT in additional jurisdictions and for additional indications; our ability to build a commercial infrastructure for HEPZATO for the treatment of mUM in the United States; obtaining regulatory approvals and complying with applicable laws and regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

Capital Commitments

Our capital commitments over the next twelve months include (a) $6.3 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement and (b) $10.6 million of loan and convertible note principal payments, if the holders do not elect to convert up to $5.0 million of the notes into equity. Additional capital commitments beyond the next twelve months include (a) $0.8 million for settlement of litigation with medac and (b) less than $0.1 million of lease liabilities.

Sources of Liquidity

ATM Sales Agreement

We entered into a Controlled Equity Offering℠ 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 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. No sales were made during the year ending December 31, 2023.

Avenue Loan Agreement

On August 6, 2021, we entered into the Avenue Loan Agreement with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue"), as amended on March 31, 2023, 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 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate pursuant to the Avenue Loan on December 31, 2023 was 16.20%. The Avenue Loan is secured by all of our assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. On March 15, 2023, we returned to Avenue $4.0 million held in the restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, we reached an agreement to amend the existing loan agreement with Avenue to defer the interest only period to September 30, 2023 with an additional extension option upon the FDA approval for the HEPZATO KIT and subsequent receipt of at least $10 million from the sale and issuance of equity securities. In exchange for this extension, the Company agreed to provide Avenue with 34,072 warrants to purchase shares of common stock. The exercise price of the warrants is $0.01. On August 14, 2023, the Company received the FDA approval for the HEPZATO KIT and subsequently received over $10 million from the exercise of warrants. At our option, we elected to extend the interest only period to December 31, 2023. Principal payments of approximately $1.0 million began in January 2024.

Private Placements, Common Offering and Warrants

On March 27, 2023, we entered into a securities purchase agreement with certain accredited investors (the "Preferred Purchase Agreement"), pursuant to which we agreed to issue and sell, in a private placement (the "Series F Preferred Offering"), (i) 24,900 shares of our Series F-1 Convertible Preferred Stock, par value $0.01 per share (the "Series F-1 Preferred Stock"), (ii) tranche A warrants (the "Preferred Tranche A Warrant") to acquire 34,859 shares of Series F-3 Convertible Preferred Stock, par value $0.01 per share (the "Series F-3 Preferred Stock") and (iii) tranche B warrants (the "Preferred Tranche B Warrant," together with the Preferred Tranche A Warrant, the "Preferred Warrants") to acquire 24,900 shares of Series F-4 Convertible Preferred Stock, par value $0.01 per share (the "Series F-4 Preferred Stock") for an aggregate offering price of $24.9 million before deducting the fees paid to the placement agent and the financial advisors and other financing expenses payable by us.

Also on March 27, 2023, we entered into a securities purchase agreement with the our Chief Executive Officer, Gerard Michel, pursuant to which we agreed to issue and sell, in a private placement (the "Common Offering", and together with the Series F Preferred Offering, the "Private Placements"), (i) 19,646 shares of common stock, (ii) tranche A warrants to acquire 31,110 shares of common stock (the "Common Tranche A Warrants", and together with the Preferred Tranche A Warrants, the "Tranche A Warrants") and (iii) tranche B warrants to acquire 16,666 shares of common stock (the "Common Tranche B Warrants", and together with the Preferred Tranche B Warrants, the "Tranche B Warrants") for an approximate aggregate offering price of $0.1 million.

On June 12, 2023, the stockholders approved the Private Placements at the annual general meeting of stockholders and therefore, the Preferred Warrants and Common Warrants issued in the Private Placements are exercisable. The exercise of all such Preferred Warrants and Common Warrants would generate approximately $60.0 million in proceeds. There can be no guarantee that all such Warrants are ever exercised, and if so, there is no guarantee that we will ever receive the full $60.0 million in proceeds. During the twelve months ended December 31, 2023, all of the Preferred Tranche A Warrants were exercised for an aggregate exercise price of $34.9 million into 34,859 shares of Series F-3 Preferred Stock and all of the Common Tranche A Warrants were exercised for an aggregate exercise price of $0.1 million into 31,110 shares of common stock.

As of December 31, 2023, 46,197 shares of our Series F-1, F-2 and F-3 Preferred Stock were converted into 12,073,145 shares of common stock.

Results of Operations

(In thousands)	Year ended December 31, 2023	2022
Total revenues	$ 2,065	$ 2,719
Cost of goods sold	(635)	(686)
Gross profit	1,430	2,033
Research and development expenses	17,502	18,583
Selling, general and administrative expenses	22,110	17,303
Total operating expenses	39,612	35,886
Operating loss	(38,182)	(33,853)
Interest and other income (expense)	(9,496)	(2,655)
Net loss	$ (47,678)	$ (36,508)

Revenue

We recorded approximately $2.1 million in product revenue during the year ended December 31, 2023. During the same period in 2022, we recorded $2.5 million in product revenue and $0.2 million in other revenue. Our product revenues decreased $0.6 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.

Cost of Goods Sold

During the year ended December 31, 2023, cost of goods sold was relatively flat between $0.6 million and $0.7 million for both 2023 and 2022.

Research and Development Expenses

For the year ended December 31, 2023, research and development expenses decreased to $17.5 million from $18.6 million for the year ended December 31, 2022, a decrease of $1.1 million or 6%. The decrease is primarily due to higher expenses for preparation of the pre-NDA meeting in April 2022 and increased third party expenses throughout 2022 related to the NDA resubmission which occurred on February 14, 2023.

Selling, General and Administrative Expenses

For the year ended December 31, 2023, selling, general and administrative expenses increased to $22.1 million from $17.3 million for the year ended December 31, 2022, an increase of $4.8 million or 28%. The increase is primarily due to increased headcount and higher costs incurred to prepare for the commercialization of HEPZATO in the United States in 2023.

Interest Expense, Net

For the year ended December 31, 2023, we recognized $1.4 million of interest expense, as compared to $2.7 million in the prior year, a decrease of $1.3 million. The decrease primarily relates to a reduction in interest expense after we returned $6.3 million to Avenue in the first quarter of 2023. The net interest was further positively affected in 2023 due to investing cash received from the Private Placements in March 2023 and the subsequent warrant exercises in August 2023.

Critical Accounting Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("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 our 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, warrant liability, a preferred stock offering, investments, and stock-based compensation.

Contingent Liabilities

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.

Warrant Liability

The valuation of the warrant liability was determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. In addition, we used probabilities of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO as inputs in the model to determine the fair value of warrants liability. We adjust the fair value of the warranty liability at the end of each reporting period.

Stock Based Compensation

Valuation of stock options generally requires certain assumptions, including the fair market 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 U.S. treasury instruments with similar remaining terms).

Accrued Expenses

We utilize contract research organizations in order to perform research and development and conduct clinical trials. In some cases, these organizations 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Delcath Systems Inc. (the "Company") and Subsidiaries as of December 31, 2023 and 2022, the related consolidated statements of income operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023 and 2022 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023 and 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

The critical audit matters communicated below are 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. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Issuance of Preferred Equity and Warrant Liabilities

Critical Audit Matter Description

As described in Note 12 to the consolidated financial statements, the Company entered into a securities purchase agreement in March 2023, in which the Company issued and sold in a private placement several classes of Series F preferred shares and warrants. We identified the evaluation of the transaction date fair value and allocation of proceeds to the preferred shares and warrants as a critical audit matter.

The principal consideration for our determination that the evaluation of the transaction date fair values and allocation of proceeds to the preferred shares and warrants was a critical audit matter is the high degree of subjective auditor judgment associated with evaluating management's determination of the fair values, which is primarily due to the complexity of the valuation models used and the sensitivity of the underlying significant assumptions. The key assumptions used within the valuation models included probabilities of successful outcomes and prospective financial information, including future revenue growth. The calculated fair values are sensitive to changes in these key assumptions.

How the Critical Audit Matter was addressed in the Audit

Our audit procedures related to the evaluation of the transaction date fair values and allocation of proceeds to the preferred shares and warrants included the following, among others:

- We evaluated the design effectiveness of certain controls over the transaction-date valuation process, including controls over the development of the key assumptions such as the revenue growth and the probabilities of success.
- We obtained the valuation report from management and the third-party specialist engaged by management.
    i. We assessed the qualifications and competence of management and the third-party specialist; and
    ii. We evaluated the methodologies used to determine the fair values of the preferred shares and warrants.
- We tested the assumptions used within the valuation model to estimate the fair values of the preferred shares and warrants, which included key assumptions such as the future revenue growth, probabilities of success and volatility.
- We assessed the reasonableness of management's forecast by inquiring with management to understand how the forecast was developed and comparing the projections to historical results and external sources including industry trends and peer companies' historical data.
- We involved an internal valuation specialist who assisted in the evaluation and testing performed of the reasonableness of significant assumptions to the models, including the applied discount rate.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 26, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 12,646	$ 7,671
Restricted cash	50	4,151
Short-term investments	19,808	—
Accounts receivable, net	241	366
Inventories	3,322	1,998
Prepaid expenses and other current assets	1,091	1,969
Total current assets	37,158	16,155
Property, plant and equipment, net	1,352	1,422
Right-of-use assets	103	285
Total assets	$ 38,613	$ 17,862
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,012	$ 2,018
Accrued expenses	5,249	4,685
Lease liabilities, current	37	186
Loan payable, current	5,239	7,846
Convertible notes payable, current	4,911	—
Total current liabilities	16,448	14,735
Warrant Liability	5,548	—
Other liabilities, non-current	840	1,144
Loan payable, non-current	—	3,070
Convertible notes payable, non-current	—	4,772
Total liabilities	22,836	23,721
Commitments and contingencies (see note 15)		
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 24,819 and 11,357 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $.01 par value; 80,000,000 shares authorized; 22,761,554 shares and 10,046,571 shares issued and outstanding at December 31, 2023 and 2022, respectively	228	100
Additional paid-in capital	520,576	451,608
Accumulated deficit	(505,162)	(457,484)
Accumulated other comprehensive income (loss)	135	(83)
Total stockholders' equity (deficit)	15,777	(5,859)
Total liabilities and stockholders' equity	$ 38,613	$ 17,862

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,	
	2023	**2022**
Product revenue	$ 2,065	$ 2,548
Other revenue	—	171
Total revenues	2,065	2,719
Cost of goods sold	(635)	(686)
Gross profit	1,430	2,033
Operating expenses:		
Research and development expenses	17,502	18,583
Selling, general and administrative expenses	22,110	17,303
Total operating expenses	39,612	35,886
Operating loss	(38,182)	(33,853)
Change in fair value of warrant liability	(7,998)	—
Interest expense, net	(1,439)	(2,685)
Other income (expense)	(59)	30
Net loss	(47,678)	(36,508)
Comprehensive (loss) income:		
Unrealized gains (loss) on investments	157	—
Foreign currency translation adjustments	61	101
Total comprehensive loss	$ (47,460)	$ (36,407)
Common share data:		
Basic and diluted loss per common share	$ (2.94)	$ (4.12)
Weighted average number of basic and diluted shares outstanding	16,229,931	8,864,615

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, 2023							
	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 Comprehensive Income (Loss)	Total
Balance at January 1, 2023	11,357	$ —	10,046,571	$ 100	$ 451,608	$ (457,484)	$ (83)	$ (5,859)
Compensation expense for issuance of stock options	—	—	—	—	8,090	—	—	8,090
Compensation expense for issuance of employee stock option plan	—	—	—	—	61	—	—	61
Private placement - issuance of common stock, net of expenses	—	—	19,646	1	55	—	—	56
Issuance of common stock with the employee stock purchase plan	—	—	41,435	—	123	—	—	123
Issuance of common stock related to stock option exercises	—	—	819	—	4	—	—	4
Preferred share issuance	44,483	—	—	—	49,487	—	—	49,487
Conversion of Series E Preferred Shares to common stock	(100)	—	10,000	—	—	—	—	—
Conversion of Series F Preferred Shares to common stock	(30,921)	—	12,073,145	122	11,148	—	—	11,270
Issuance of common stock with common stock warrant exercises	—	—	569,938	5	—	—	—	5
Net loss	—	—	—	—	—	(47,678)	—	(47,678)
Unrealized gain on investments	—	—	$ —	—	—	—	157	157
Foreign currency translation adjustments	—	—	—	—	—	—	61	61
Balance at December 31, 2023	24,819	$ —	22,761,554	$ 228	$ 520,576	$ (505,162)	$ 135	$ 15,777

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC
Consolidated Statements of Stockholders' Equity (Deficit), Continued
(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 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 stock and prefunded warrants, net of expenses	—	—	2,139,843	21	10,836	—	—	10,857
Net loss	—	—	—	—	—	(36,508)	—	(36,508)
Foreign currency translation adjustments	—	—	—	—	—	—	(101)	(101)
Balance at December 31, 2022	11,357	$ —	10,046,571	$ 100	$ 451,608	$ (457,484)	$ (83)	$ (5,859)

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (47,678)	$ (36,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	8,151	7,941
Depreciation expense	128	132
Warrant liability fair value adjustment	7,998	—
Non-cash lease expense	271	443
Amortization of debt discount	776	768
Interest expense accrued related to convertible notes	160	160
Amortization of premiums and discounts on marketable securities	(151)	—
Changes in assets and liabilities:		
Prepaid expenses and other assets	1,029	774
Accounts receivable	125	(322)
Inventory	(1,324)	(587)
Accounts payable and accrued expenses	(199)	1,798
Other liabilities, non-current	(537)	621
Deferred revenue	—	(170)
Net cash used in operating activities	(31,251)	(24,950)
Cash flows from investing activities:		
Purchases of investments	(19,651)	—
Sales and maturities of investments	—	—
Purchase of property, plant and equipment	(58)	(209)
Net cash used in investing activities	(19,709)	(209)
Cash flows from financing activities:		
Net proceeds from private placement	22,960	10,857
Proceeds from the issuance of common stock relating to the employee stock purchase plan	123	—
Repayment of Debt	(6,313)	(714)
Proceeds from the exercise of warrants	35,004	—
Proceeds from the exercise of stock options	4	—
Net cash provided by financing activities	51,778	10,143
Foreign currency effects on cash	56	(115)
Net increase (decrease) in total cash	874	(15,131)
Total Cash, Cash Equivalents and Restricted Cash:		
Beginning of period	11,822	26,953
End of period	$ 12,696	$ 11,822
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash	$ 12,646	$ 7,671
Restricted Cash	50	4,151
Total	$ 12,696	$ 11,822

	Years Ended December 31,	
	2023	**2022**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 1,459	$ 1,873
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right of use assets obtained in exchange for lease obligations	$ 84	$ 86
Conversion of mezzanine equity to common shares	$ 11,269	$ —
Conversion of mezzanine equity to preferred shares	$ 7,099	$ —

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
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(1) Description of Business

The Company is an interventional oncology company focused on the treatment of primary and cancers metastatic to the liver. The Company's lead product, the HEPZATO™ KIT ("HEPZATO" melphalan for Injection/Hepatic Delivery System), a drug/device combination product, was approved by the US Food and Drug Administration (the "FDA") on August 14, 2023, indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection, or radiation. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as 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 in the liver. The first commercial use of HEPZATO for the treatment of mUM occurred in January 2024.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by 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).

The Company has sufficient raw material and component constituent parts of HEPZATO KIT to meet the first year of its anticipated demand and it intends to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

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

The Company's clinical development program for HEPZATO was comprised of the FOCUS Clinical Trial for Patients with metastatic hepatic dominant Uveal Melanoma (the "FOCUS Trial"), a global registration clinical trial that investigated objective response rate in patients with metastatic uveal melanoma ("mUM"). The current focus of the Company's clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in patients with mUM, either as monotherapy or in combination with immunotherapy. The Company extects that this will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support reimbursement in various jurisdictions, including the United States. In addition to HEPZATO's use to treat mUM, the Company believes that HEPZATO has the potential to treat cancers in the liver, such as metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic breast cancer and intrahepatic cholangiocarcinoma, and plans to begin one or more studies of HEPZATO KIT to treat such conditions in 2024. The Company believes that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the risks associated with developing product candidates and successfully launching and commercializing its drug/device combination products, the Company's ability to obtain regulatory approval of its such products in the United States and other geography markets, the uncertainty of the broad adoption of its approved products by physicians and consumers, and significant competition.

In addition, high rates of inflation have resulted in the U.S. Federal Reserve raising interest rates. 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. Furthermore, if additional banks and financial

institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company or its partners' ability to access existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on the Company's business and financial condition, including the Company's ability to access additional capital on favorable terms, or at all, which could in the future negatively affect the Company's ability to pursue its business strategy.

Liquidity and Going Concern

On December 31, 2023, the Company had cash, cash equivalents and restricted cash totaling $12.7 million and short-term investments totaling $19.8 million, as compared to cash, cash equivalents and restricted cash totaling $11.8 million at December 31, 2022. During the twelve months ended December 31, 2023, the Company used $31.3 million of cash in its operating activities and $6.3 million for principal payments.

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance that it will ever achieve or maintain profitability. The Company has historically funded its operations primarily with proceeds from sales of common stock, warrants and prefunded warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

If there is a substantial delay in the activation of sites approved to administer HEPZATO, the Company expects to need to raise additional capital under structures available to the Company, including debt and/or equity offerings, which may not be on favorable terms. In a substantially delayed site activation scenario, the Company would not have sufficient funds to meet its obligations within twelve months from the issuance date of these condensed consolidated financial statements. As such, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt about the Company's ability to continue as a going concern. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises funds through collaborations, or other similar arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company and/or may reduce the value of its common stock. If the Company is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market its product candidates even if the Company would otherwise prefer to develop and market such product candidates itself.

The Company also expects to use cash and cash equivalents to fund activities relating to commercial support for HEPZATO, CHEMOSAT and any future clinical research trials and operating activities. The Company's future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining 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.

The Company's capital commitments over the next twelve months include (a) $6.3 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement and (b) $10.6 million of loan and convertible note principal payments, if the holders do not elect to convert up to $5.0 million of the notes into equity. Additional capital commitments beyond the next twelve months include (a) less than $0.1 million of lease liabilities; and (b) $0.8 million for settlement of litigation with medac.

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(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.

Investments

Investments classified as short-term have maturities of less than one year. Investments classified as long-term are those that: (i) have a maturity of greater than one year, and (ii) the Company does not intend to liquidate within the next twelve months, although these funds are available for use and, therefore, are classified as available-for-sale. The Company's investment strategy is to buy short-duration Treasury bills (T-bills). As of December 31, 2023, all investments held by the Company had remaining contractual maturities of less than five months.

Accounts Receivable

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

Inventories

Inventories are valued at the lower of cost or 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.

Leases

The Company determines if an arrangement is a lease at inception, in accordance with Accounting Standards Codification ("ASC") Topic 842, Leases. All operating lease commitments with a lease term greater than 12 months are recognized as right-of-use assets and lease liabilities, on a discounted basis on the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Certain of the Company's lease agreements include lease payments that are adjusted periodically for an index or rate. The leases are initially measured using the present value of the projected payments adjusted for the index or rate in effect at the commencement date. In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance and other expenses, which do not transfer a good or service to the Company and are generally referred to as non-lease components. Variable non-lease components are not measured as part of the right-of-use asset and liability. Only when lease components and their associated non-lease components are fixed are they accounted for as a single lease component and are recognized as part of a right-of-use asset and liability. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company may have options to renew lease terms for facilities and other assets. Some leases contain clauses for renewal at the Company's option with renewal terms that generally extend the lease term from 1 to 5 years. The exercise of lease renewal options is generally at the Company's sole discretion. The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option on the basis of economic factors.

Fair Value Measurements

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

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

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

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

Revenue Recognition

Revenue is generated from proprietary and partnered product sales and license and royalty arrangements. Revenue is recognized when or as 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.

The Company 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. 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 significant changes in estimates could impact the Company's results of operations in future periods. The Company's total revenue and accounts receivable concentration from a CHEMOSAT customer for the year ended and as of December 31, 2023 was 16.1% and 21.1%, respectively, and 20.8% and 41.6%, respectively for the year ended December 31, 2022.

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 15 – 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, 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, personnel costs associated with device and pharmaceutical development expenses, 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, which is 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 market value of the common stock at the date of the grant. The Company estimates the fair value of stock options using the Black-Scholes 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 17 for additional information.

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 26, 2024, which is the date the consolidated financial statements were issued, determining all subsequent events have been disclosed.

Recently Issued Accounting Pronouncements

ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The disclosure requirements must be applied retrospectively to all prior periods presented in the financial statements. The effective date for the standard is for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

ASU 2023-09, Improvements to Income Tax Disclosures

On December 14, 2023, the FASB issued, ASU 2023-09, Improvements to Income Tax Disclosures, a final standard on improvements to income tax disclosures. The standard requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard applies to all entities subject to income taxes and is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. For public business entities (PBEs), the new requirements will be effective for annual periods beginning after December 15, 2024. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively. The Company is currently in the process of evaluating the effect of this guidance on its financial statements.

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(4) 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, 2023	December 31, 2022
Cash and cash equivalents	$ 12,646	$ 7,671
Restricted balance for loan agreement	—	4,000
Letters of credit	—	101
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 12,696	$ 11,822

On March 15, 2023, the Company returned to Avenue the $4.0 million held in restricted cash to pay down a portion of the outstanding Avenue Loan balance. See Note 11 - Loans and Convertible Notes Payable - Term Loan from Avenue Venture Opportunities Fund, L.P. for more information. On March 31, 2023, the letter of credit for the sub-lease agreement for office space at 1633 Broadway, New York, NY expired.

(5) Investments

Marketable debt securities held by the Company are classified as available-for-sale pursuant to ASC 320, Investments - Debt and Equity Securities, and carried at fair value in the accompanying condensed consolidated balance sheets.

The following table summarizes the gross unrealized gains and losses on the Company's marketable securities:

	December 31, 2023				
		Gross Unrealized			
	Amortized Cost	Gains	Losses	Credit Losses	Estimated Fair Value
U.S. government agency bonds	$ 19,651	$ 157	$ —	$ —	$ 19,808
	$ 19,651	$ 157	$ —	$ —	$ 19,808
Classified as:					
Short-term investments					$ 19,808

As of December 31, 2023, there was $0.2 million of interest receivable related to the outstanding debt securities held by the Company.

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(6) Inventories

Inventories consist of:

	December 31, 2023	December 31, 2022
Raw materials	$ 1,443	$ 763
Work-in-process	1,753	1,102
Finished goods	126	133
Total inventories	$ 3,322	$ 1,998

(7) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

	December 31, 2023	December 31, 2022
Clinical trial expenses	$ 222	$ 1,630
Insurance premiums	157	123
Professional services	133	121
Interest Receivable	151	—
Other	428	95
Total prepaid expenses and other current assets	$ 1,091	$ 1,969

(8) Property, Plant, and Equipment

Property, plant, and equipment consists of:

	December 31, 2023	December 31, 2022	Estimated Useful Life
Buildings and land	$ 1,318	$ 1,301	30 years - Buildings
Enterprise hardware and software	1,857	1,855	3 years
Leaseholds	1,787	1,774	Lesser of lease term or estimated useful life
Equipment	1,263	1,222	7 years
Furniture	202	201	5 years
Property, plant and equipment, gross	6,427	6,353	
Accumulated depreciation	(5,075)	(4,931)	
Property, plant and equipment, net	$ 1,352	$ 1,422	

Depreciation expense for the years ended December 31, 2023 and 2022 was $0.1 million and $0.1 million, respectively.

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(9) Accrued Expenses

Current accrued expenses include the following:

	December 31, 2023	December 31, 2022
Clinical expenses	$ 1,129	$ 1,470
Compensation, excluding taxes	1,859	1,040
Professional fees	272	1,087
Interest on convertible note	713	553
Inventory	585	—
Other	691	535
Total accrued expenses	$ 5,249	$ 4,685

(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.

On June 25, 2020, the Company entered into a sub-lease agreement (the "2021 Sub-Lease") with its previous sub-lessee pursuant to which, effective August 2, 2021, the previous sub-lessee would become the lessee and the Company would then sublease its portion of the premises in Galway, Ireland from the previous sub-lessee. The Company's rent expense under the 2021 Sub-Lease is approximately $3,700 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 amendments was extended through August 2023. As of August 31, 2023, this lease has been on a month-to-month basis. No ROU assets or lease liabilities are recognized on the balance sheet for this arrangement. The Company ended the sublease for its former corporate offices at 1633 Broadway, New York, NY in February 2024.

For the years ended December 31, 2023 and 2022, lease expense of less than $0.2 million and $0.1 million, respectively, was recorded for short-term leases.

The following table summarizes the Company's operating leases as of December 31, 2023:

	U.S.	Ireland	Total
Lease cost			
Operating cash flows from operating leases	$ 238	$ 33	$ 271
Weighted average remaining lease term	—	2.6	
Weighted average discount rate - operating leases	8%	8%	

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

	U.S.	Ireland	Total
Year ended December 31, 2024	$ —	$ 44	$ 44
Year ended December 31, 2025	—	44	44
Year ended December 31, 2026	—	26	26
Total	—	114	114
Less present value discount	—	(11)	(11)
Operating lease liabilities included in the condensed consolidated balance sheets at December 31, 2023	$ —	$ 103	$ 103

(11) Loans and Convertible Notes Payable

	December 31, 2023			December 31, 2022		
	Gross	Discount	Net	Gross	Discount	Net
Loans payable, current	$ 5,610	$ (371)	$ 5,239	$ 8,570	$ (724)	$ 7,846
Loans payable, non-current	—	—	—	3,353	(283)	3,070
Total - Loans payable[1]	$ 5,610	$ (371)	$ 5,239	$ 11,923	$ (1,007)	$ 10,916
Convertible notes payable - current	5,000	(89)	4,911	—	—	—
Convertible notes payable - non-current	—	—	—	5,000	(228)	4,772
Total - Convertible notes payable	$ 5,000	$ (89)	$ 4,911	$ 5,000	$ (228)	$ 4,772
Total - Loans and notes payable	$ 10,610	$ (460)	$ 10,150	$ 16,923	$ (1,235)	$ 15,688

[1] The gross amount includes the 4.25% final payment of $0.5 million.

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

	Loans	Convertible Notes	Total
Year ended December 31, 2024	$ 5,610	$ 5,000	$ 10,610
Year ended December 31, 2025	—	—	—
Total	$ 5,610	$ 5,000	$ 10,610

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, 2023 was 16.2%. 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 was $15.0 million, including $4.0 million that was funded into a restricted account. On March 15, 2023, the Company returned to Avenue $4.0 million held in the restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, the Avenue Loan Agreement was amended (the "Avenue Amendment") to defer the interest only period to September 30, 2023, with an additional extension option upon FDA Approval for the HEPZATO KIT and subsequent receipt of at least $10 million from the sale and issuance of equity securities. On August 14, 2023, the Company received FDA approval and has subsequently received over $10 million from the exercise of Tranche A Preferred Warrants. At the Company's option, it has elected to extend the interest only period to December 31, 2023 and principal payments began in January 2024.

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

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 judgements.

In connection with the initial entry into the Avenue Loan Agreement, the Company issued warrants to Avenue (the "Initial Avenue Warrant") to purchase 127,755 shares of common stock at an exercise price per share equal to $0.01. The Initial Avenue Warrant is exercisable until August 31, 2026. Additionally, in connection with the Avenue Amendment, the Company issued to Avenue a warrant to purchase 34,072 shares of common stock at an exercise price per share equal to $0.01.

The Company determined that the embedded conversion option associated with the Avenue Loan did not require bifurcation and met the criteria for equity classification. In addition, the amendment was recorded under debt modification guidance. Aggregate debt discount amortization of $0.8 million was recorded for the years ended December 31, 2023 and 2022. Interest expense incurred was $1.5 million and $1.9 million for the years ended December 31, 2023 and 2022, respectively.

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 (i) reduce the conversion price to $1,198 per share of the Company's Series E Convertible Preferred Stock; and (ii) extend the maturity date to October 30, 2024. In addition, the holders of the Rosalind Notes agreed to subordinate all of the Company's indebtedness and obligations to Avenue and all of the holders' security interest, to the Avenue Loan and Avenue's security interest in the Company's property.

Interest expense relating to the Rosalind Notes was $0.2 million for the years ended December 31, 2023 and 2022.

(12) Preferred Purchase Agreement

On March 27, 2023, the Company entered into a securities purchase agreement with certain accredited investors (the "Preferred Purchase Agreement"), pursuant to which on March 29, 2023, the Company issued and sold, in a private placement (the "Series F Preferred Offering"), (i) 24,900 shares of Series F-1 Convertible Preferred Stock, par value $0.01 per share (the "Series F-1 Preferred Stock"), (ii) tranche A warrants (the "Preferred Tranche A Warrants") to acquire 34,859 shares of Series F-3 Convertible Preferred Stock, par value $0.01 per share (the "Series F-3 Preferred Stock") and (iii) tranche B warrants (the "Preferred Tranche B Warrants", together with the Preferred Tranche A Warrants, the "Preferred Warrants") to acquire 24,900 shares of Series F-4 Convertible Preferred Stock, par value $0.01 per share (the "Series F-4 Preferred Stock") for an aggregate offering price of $24.9 million before deducting

the fees paid to the placement agent and the financial advisors and other financing expenses payable by the Company.

The gross proceeds of $24.9 million from the Series F Preferred Offering have been allocated first to the Preferred Warrant liabilities at their fair value of $4.9 million, with the residual of $20.0 million being allocated to the Series F-1 Preferred Stock.

During the twelve months ended December 31, 2023, all of the Preferred Tranche A Warrants were exercised for an aggregate exercise price of $34.9 million into 34,859 shares of Series F-3 Preferred Stock and since then 23,839 shares of F-3 Preferred Stock were converted into 5,297,550 shares of common stock. The Preferred Tranche B Warrants are exercisable for 24,900 shares of Series F-4 Preferred Stock, with an aggregate exercise price of $24.9 million until the earlier of (i) 21 days following the Company's announcement of receipt of at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO and (ii) March 31, 2026.

Following stockholder approval, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series F-1 Preferred Stock automatically converted into shares of common stock and/or, if applicable (in accordance with the beneficial ownership limitations then in effect), shares of Series F-2 Preferred Stock, par value $0.01 per share (the "Series F-2 Preferred Stock" and, together with the Series F-1 Preferred Stock, the Series F-3 Preferred Stock and the Series F-4 Preferred Stock, the "Series F Preferred Stock") in lieu of common stock. Subject to limitations set forth in the Certificate of Designation, the shares of Series F-2, F-3 and F-4 Preferred Stock are convertible into common stock at the option of the holder at the conversion price of $3.30 per share, $4.50 per share and $6.00 per share, respectively, rounded down to the nearest whole share, and in each case subject to the terms and limitations contained in the Certificate of Designation. During the twelve months ended December 31, 2023, 46,197 shares of the Company's Series F-1, F-2 and F-3 Preferred Stock were converted into 12,073,145 shares of common stock. As of December 31, 2023, there were 2,542 shares of Series F-2 Preferred Stock, 11,020 shares of Series F-3 Preferred Stock and no shares of Series F-4 Preferred Stock outstanding.

The Series F-2, F-3 and F-4 Preferred Stock are not mandatorily redeemable, redeemable at the holder's election or contingently redeemable at the holder's election (at this point, a Deemed Liquidation Event would potentially trigger pro rata liquidation payments to the preferred and common stockholders on a pro rata "as converted" basis). Accordingly, the Series F-2, F-3 and F-4 Preferred are now classified as permanent equity.

The Company determined that the outstanding Preferred Warrants should be liability-classified. See *Critical Accounting Estimates - Fair Value Measurements - Warrant Liability* for a discussion of the accounting treatment of the Common Warrants and Preferred Warrants.

(13) Stockholders' Equity

Public and Private Placements

Common Purchase Agreement

On March 27, 2023, the Company entered into a securities purchase agreement (the "Common Purchase Agreement") with the Company's Chief Executive Officer, Gerard Michel, pursuant to which the Company agreed to issue and sell, in a private placement (the "Common Offering") shares of common stock, tranche A warrants ("Common Tranche A Warrants") to acquire 31,110 shares of common stock, tranche B warrants ("Common Tranche B Warrants", together with the Common Tranche A Warrants, the "Common Warrants") to acquire 16,666 shares of common stock. On March 29, 2023, the Company closed the Common Offering.

The aggregate exercise price of the Common Tranche A Warrants issued pursuant to the Common Offering is approximately $0.1 million.

On August 14, 2023, the Company announced the receipt of the FDA Approval and all Common Tranche A Warrants were exercised and converted into 31,110 shares of common stock.

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The aggregate exercise price of the Common Tranche B Warrants issued in the Common Offering is approximately $0.1 million. The Common Tranche B Warrants are exercisable for an aggregate of 16,666 shares of common stock until the earlier of 21 days following the Company's announcement of receipt of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO and March 31, 2026.

Registration Rights for Preferred and Common Offerings

Pursuant to the Preferred Purchase Agreement and the Common Purchase Agreement (collectively, the "Purchase Agreements"), the Company filed a registration statement on Form S-3 (the "Resale Registration Statement") providing for the resale by the investors party thereto of the common stock issuable upon conversion of the Registrable Shares (as defined in the Purchase Agreements). The Resale Registration Statement became effective on June 28, 2023.

There is no established public trading market for the Series F Preferred Stock, the Preferred Warrants, or the Common Warrants and the Company does not intend to list such securities on any national securities exchange or nationally recognized trading system.

At-the-Market Offering

The Company has entered into a Controlled Equity Offering[SM] Sales Agreement ("ATM Sales Agreement"), with Cantor Fitzgerald & Co. (the "Sales Agent"), pursuant to which the Company may offer and sell, at its sole discretion through the Sales Agent, shares of common stock having an aggregate offering price of up to $17.0 million. To date, the Company has sold approximately $4.0 million of its common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the year ended December 31, 2023.

Authorized Shares

In June 2023, stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the total number of shares of its common stock authorized for issuance from 40 million to 80 million shares. The company is authorized to issue 80 million shares of common stock, $0.01 par value, and 10 million shares of preferred stock, $0.01 par value. As of December 31, 2023, the Company has designated the following preferred stock:

Designated Preferred Shares	December 31, 2023
Series A	4,200
Series B	2,360
Series C	590
Series D	10,000
Series E	40,000
Series E-1	12,960
Series F-1	24,900
Series F-2	24,900
Series F-3	34,860
Series F-4	24,900
Total	179,670

Preferred Stock

As of December 31, 2023, there were an aggregate of 11,257 shares of Series E and Series E-1, 2,542 Series F-2 and 11,020 Series F-3 Convertible Preferred Stock outstanding, respectively.

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Equity Incentive Plans

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. On June 12, 2023, the stockholders approved the amendment to the Company's 2020 Plan to increase the number of shares of common stock available under the plan by 2.65 million shares. The 2020 Plan provides for the grant of 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, 2023, there are 5,123,742 shares of common stock reserved under the 2020 Plan for future issuance, of which 1,837,509 remained available to be granted.

In addition to options granted from the 2020 Plan, the Company also grants employment inducement awards pursuant to Listing Rule 5635(c)(4) of the corporate governance rules of the NASDAQ Stock Market. The inducement grants are intended to provide incentive to certain individuals to enter into employment with the Company. Prior to December 5, 2023, the inducement awards were granted outside of the 2020 Plan, however they are governed in all respects as if they were issued under the 2020 Plan. These grants do not reduce the number of options available for issuance under the 2020 Plan.

On December 5, 2023, the Company's 2023 Inducement Plan (the "2023 Plan") was adopted by the Company's Board of Directors. The 2023 Plan is administered by a Compensation Committee of two or more Independent Directors appointed by the Board of Directors and is intended to provide for the grant of 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 appropriate to incentivize employment with the Company. Awards from the 2023 Plan can only be granted to individuals who have not previously worked for the Company or have not worked for the Company for a bona fide period of time. As of December 31, 2023, there are 650,000 shares of common stock reserved under the 2023 Plan, of which 623,000 remain available to be granted.

Stock Options

The following table sets forth information as of December 31, 2023 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	3,286,233	$ 7.69	1,837,509
Equity compensation plans not approved by security holders [1]	896,999	$ 9.93	623,000
Total	4,183,232	$ 8.17	2,460,509

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(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, non-qualified 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 non-qualified 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; and (c) new hire inducement awards to purchase 398,500 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 12 employees hired during 2022 and 2023.

The following tables include information for all options granted, including inducement grants that are granted outside of the 2020 Plan.

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	
	2023	2022
Expected terms (years)	0.8 - 5.9	0.7 - 8.4
Expected volatility	96.4% -172.8%	166.4.% - 180.3%
Risk-free interest rate	3.9% - 5.4%	1.2% - 4.4%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the stock options granted during the years ended December 31, 2023 and 2022 was approximately $5.62 and $6.05 per share, respectively.

The following is a summary of stock option activity for the year ended December 31, 2023:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2023	2,235,052	$ 10.30	$ 9.40	7.7	$ 36
Granted	2,218,757	5.97	5.62	9.1	
Exercised	(819)	4.67	4.51		$ 1
Expired	(141,059)	8.40	5.76		
Cancelled/Forfeited	(128,699)	7.02	6.74		
Outstanding at December 31, 2023	4,183,232	$ 8.17	$ 7.60	8.3	$ 147
Exercisable at December 31, 2023	2,252,556	$ 9.93	$ 9.15	7.6	$ 24
Unvested at December 31, 2023	1,930,676	$ 6.12	$ 5.79	9.1	$ 123

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The following table summarizes information for stock option shares outstanding and exercisable at December 31, 2023:

		Options Exercisable	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
2.83 - $51.50	4,182,733	8.3	2,252,057
51.50+	499	5.1	499
	4,183,232	8.3	2,252,556

The following is a summary of the share-based compensation expense in the statement of operations for the twelve months ended December 31, 2023:

	Years Ended December 31,	
	2023	2022
Selling, general and administrative	$ 4,944	$ 5,282
Research and development	2,837	2,449
Cost of goods sold	370	210
Total	$ 8,151	$ 7,941

At December 31, 2023, there was approximately $5.9 million of aggregate unrecognized compensation expense related to employee, consultant and Non-employee Director stock option grants. The Company does not estimate forfeitures and only recognizes forfeitures as they occur. The cost is expected to be recognized over a weighted average period of 2.1 years.

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 of which 41,435 have been issued as of December 31, 2023 since the inception of the benefit in 2021. 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 2024, an aggregate 21,140 shares were purchased by participating employees for the offering period of July 3, 2023 to December 29, 2023.

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Common Stock Warrants

The following is a summary of common stock warrant activity for the year ended December 31, 2023:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2023	5,153,291	$ 7.01	
Warrants issued	81,848	2.94	
Warrants exercised	(569,938)	$ 0.26	
Outstanding at December 31, 2023	4,665,201	$ 7.76	1.6
Exercisable at December 31, 2023	4,665,201	$ 7.76	1.6

The following table presents information related to stock warrants at December 31, 2023:

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$0.01	1,037,792	3.2	1,037,792
$6.00	16,666	2.2	16,666
$10.00	3,610,743	1.2	3,610,743
	4,665,201	1.6	4,665,201

Preferred Stock Warrants

The following is a summary of preferred stock warrant activity for the year ended December 31, 2023:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2023	—	$ —	
Warrants issued	59,759	1,000.00	
Warrants exercised	(34,859)	$ 1,000.00	
Outstanding at December 31, 2023	24,900	$ 1,000.00	2.3
Exercisable at December 31, 2023	24,900	$ 1,000.00	2.3

(14) Net Loss Per 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

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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.

For the years ended December 31, 2023 and 2022 the following potentially dilutive securities were excluded from the computation of diluted earnings per share because their effects would be antidilutive:

	December 31,	
	2023	2022
Common stock warrants - equity	3,627,409	3,610,743
Assumed conversion of preferred stock warrants	4,149,994	—
Assumed conversion of preferred stock	4,344,909	1,135,721
Assumed conversion of convertible notes	488,031	488,031
Stock options	4,183,232	2,235,052
Total	16,793,575	7,469,547

At December 31, 2023, the Company had 1,037,792 pre-funded warrants outstanding. The following tables provides a reconciliation of the weighted average shares outstanding calculation for the year-ended December 31, 2023 and 2022.

	Year ended December 31,	
	2023	2022
Weighted average shares issued	15,039,630	8,290,529
Weighted average pre-funded warrants	1,190,301	574,086
Weighted average shares outstanding	16,229,931	8,864,615

(15) Commitments and Contingencies

Litigation, Claims and Assessments

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 certain designated countries 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. On December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution procedures of the medac Agreement for the non-payment of the invoice.

On December 30, 2022, the parties reached a final settlement of the matter and the Company agreed to pay medac either (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, or (b) a minimum annual payment of $0.2 million in the event the annual royalty payment does not reach the agreed minimum payment amount. As of December 31, 2023, the Company has estimated the settlement to be $1.0 million and recorded $0.8 million as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet.

Lachman Consulting Services, Inc

On January 24, 2023, Lachman Consultant Services, Inc. ("Lachman") served the Company with a complaint alleging that Delcath owed Lachman approximately $0.9 million in unpaid consulting fees plus interest, costs and attorneys' fees. The dispute arises from a July 22, 2021 agreement between Lachman and Delcath under which Lachman provided assistance to the Company in regard to preparing for a FDA inspection and good manufacturing practices, training and support. A settlement was reached on July 5, 2023, under which the Company paid Lachman $0.9 million.

Manufacturing and Supply Agreements

The Company has a License, Supply and Contract Manufacturing Agreement (the "Supply Agreement") for the supply of melphalan provided in the HEPZATO KIT. The Supply Agreement is effective until April 30, 2024, with an option to extend its term for three additional years. The Supply Agreement does not consist of minimum purchase units per year but does require each order to contain a minimum number of vials. As of December 31, 2023, the Company has committed to purchase $2.25 million of melphalan under this Supply Agreement in 2024.

(16) Subsequent Events

Leases

On January 18, 2024 (the "Lease Commencement Date"), the Company entered into a lease agreement (the "Queensbury Lease") to lease approximately 18,000 square feet of manufacturing and office space in Queensbury, New York (the "Premises"). The initial term of the lease is 5 years with a right to extend the lease by an additional 5 years, exercisable under certain conditions set forth in the Queensbury Lease. The initial term is expected to begin within 90 days of the Lease Commencement Date.

The annual base rent of the Queensbury Lease is initially $8 per square foot per year, subject to annual 3% increases in years four and five. Additionally, the Company is responsible for reimbursing the landlord for the Company's share of the Premises' property taxes.

Securities Purchase Agreement

On March 14, 2024, the Company and certain accredited investors (each an "Investor" and collectively, the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company agreed to sell and issue to the Investors in a private placement (the "Private Placement") (i) an aggregate of 876,627 shares (the "Shares") of the Company's common stock, par value $0.01 per share (the "Common Stock"), at a purchase price of $3.72 per share, and (ii) to certain investors, in lieu of shares of Common Stock, 1,008,102 pre-funded warrants (the "Pre-Funded Warrants") at a price per Pre-Funded Warrant of $3.71 (the "Warrant Shares" and together with the Shares, the "Securities"). The Pre-Funded Warrants will have an exercise price of $0.01 per share of Common Stock, be immediately exercisable and remain exercisable until exercised in full.

The Private Placement closed on March 19, 2024. The Company received gross proceeds from the Private Placement of approximately $7.0 million, before deducting 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.

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(17) Income Taxes

There is no income tax provision for the years ended December 31, 2023 and 2022, respectively.

Loss before income taxes consists of:

	For the Year Ended December 31,	
	2023	2022
Domestic	$ (41,303)	$ (34,547)
Foreign	(6,375)	(1,960)
Income before taxes	$ (47,678)	$ (36,507)

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

	For the Year Ended December 31,	
	2023	2022
Income taxes using U.S federal statutory rate	$ (10,012)	$ (7,666)
Nondeductible interest	127	139
Branch income	(1,230)	(385)
State income taxes, net of federal benefit	(31)	(531)
Foreign rate differential	506	165
Valuation allowance	7,099	9,221
Stock option expense, exercises and cancellations	2,899	752
Research and development costs	(859)	(708)
Other	(179)	(987)
Derivative Charge	1,680	—
	$ —	$ —

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

	For the Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Employee compensation accruals	$ 1,377	$ 2,772
Accrued liabilities	54	197
Research tax credits	2,330	1,429
Lease obligation	4	38
Other	233	160
Research expense capitalization	5,441	3,203
Net operating losses	29,875	24,595
Total deferred tax assets	$ 39,314	$ 32,394

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	For the Year Ended December 31,	
	2023	2022
Deferred tax liabilities:		
Right of use asset	$ 13	$ 50
Total deferred tax liabilities	13	50
Valuation allowance	39,301	32,344
Net deferred tax assets	$ —	$ —

As of December 31, 2023, and 2022, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $307.6 million and $290.4 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, 2021 and 2023, 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 $200.5 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $107.1 million of net operating loss carryforwards remains available to offset future federal taxable income, of which $1.7 million will expire between 2024 and 2037 and $105.4 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, 2023, and 2022, the Company had net operating loss carryforwards for states and city income tax purposes between approximately $0.8 million and $196.0 million and between approximately $0.3 million and $195.3 million, respectively, which expire through 2043. As a result of the Section 382 limitations, approximately $191.1 million and $175.4 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 $5.0 million and $4.9 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2023 and 2022, the Company had a net operating loss carryforward for foreign income tax purposes of $43.3 million and $33.4 million, respectively, which have indefinite carryforward periods. As of December 31, 2023 and 2022, the Company had federal research and development tax credit carryforwards of approximately $7.4 million and $6.5 million, respectively, which expire through 2043. As a result of the Section 382 limitations, all but $2.3 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 $7.0 million and $9.2 million in 2023 and 2022, respectively. The change in valuation allowance is as follows:

	December 31,	
	2023	2022
Beginning Balance	$ 32,344	$ 23,125
Charged to costs and expenses	7,099	9,221
Charged to other comprehensive income	(142)	(2)
Ending balance	$ 39,301	$ 32,344

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
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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 United States, 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, 2020; tax years ending December 31, 2020 through December 31, 2023 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, 2023); tax years ending December 31, 2019 through December 31, 2023 remain open to examination. However, the Company's tax years December 31, 1998 through December 31, 2023 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

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

The Company's foreign subsidiaries have generally incurred losses since inception and the Company has no material undistributed earnings as of December 31, 2023.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
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(18) Fair Value Measurements

The Company's fair value measurements are classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The table below presents activity within Level 3 of the fair value hierarchy and the Company's liabilities carried at fair value for the year ended December 31, 2023:

	Level 3		
	Contingent Liabilities	Warrant Liabilities	Total
Balance at January 1, 2023	$ 1,280	$ —	$ 1,280
Fair value of warrant liabilities issued	—	4,940	4,940
Total change in exchange rate	46	—	46
Fair value adjustment	(330)	1,688	1,358
Change due to warrant exercise	—	(1,080)	(1,080)
Balance at December 31, 2023	$ 996	$ 5,548	$ 6,544

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 the Company's 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.

As disclosed in Note 12 of the Company's consolidated financial statements, the Company allocated part of the proceeds of the Series F Preferred Offering to warrant liability issued in connection with the transaction. The valuations of the warrants were determined using option pricing models. The Company concluded that the Preferred Warrants were not in the scope of ASC 480, Distinguishing Liabilities from Equity, since the Preferred Warrants are not mandatorily redeemable; and do not have obligations to issue a variable number of shares of preferred stock. The Company determined the Preferred Warrants met the definition of a derivative in accordance with ASC 815 but were not considered indexed to the Company's common stock since the warrants require early settlement by repurchasing the preferred warrants for cash in an amount equal to the Black-Scholes value in the event of a Fundamental Transaction at pre-specified volatility of 100% as an input to the Black-Scholes calculation. The Company determined to record the Preferred Warrants at fair value with subsequent changes in fair value recorded in earnings at the end of each reporting period. For the twelve months ended December 31, 2023, the Company recorded other expense of $8.0 million related to the change in fair value of the warrant liability and Tranche A Warrant exercises. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the warrants as a long-term liability due to certain provisions relating to the holders' ability to exercise the warrants beyond twelve months of the reporting date.

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The fair value of the preferred and common warrants at December 31, 2023 and March 29, 2023 was determined by using option pricing models assuming the following:

	March 29, 2023	December 31, 2023
Risk free interest rate	3.80% - 4.80%	4.09%
Expected term (years)	0.5 - 3.0	2.3
Expected volatility	70% - 75%	70%
Expected dividends	0.00%	0.00%

Additionally, the Company has determined that the warrant liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing models against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of the Company's stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of the Company's stock over that term; annual rate of dividends; and the risk-free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of the Company's stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market, the risk-free rate of return is a Level 2 input, while the historical volatility is a Level 3 input as defined in ASC 820-10. Since the lowest level input is a Level 3, the Company determined the warrant liability is most appropriately classified within Level 3 of the fair value hierarchy.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2023 and December 31, 2022 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value.

	December 31, 2023				December 31, 2022			
Description	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:								
Money market funds	$ 392	$ —	$ —	$ 392	$ —	$ —	$ —	$ —
U.S. government agency bonds	—	19,808	—	19,808	—	—	—	—
Total Assets	392	$ 19,808	$ —	$ 20,200	$ —	$ —	$ —	$ —
Liabilities:								
Contingent Liability	$ —	$ —	$ 996	$ 996	$ —	$ —	$ 1,280	$ 1,280
Warrant Liabilities	—	—	5,548	5,548	—	—	—	—
Total Liabilities	$ —	$ —	$ 6,544	$ 6,544	$ —	$ —	$ 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 effective as of December 31, 2023.

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 effective as of December 31, 2023.

The Remediation of Material Weakness

Management, with the input, oversight and support of our audit committee, has completed the following steps, which management believes assisted us in remediating the material weakness in our internal control over financial reporting relating to the detection and application of our expense policy of share-based compensation as further described in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 27, 2023.

a. As of April 2023, the stock option expense platform utilized by the Company was updated to appropriately expense share-based compensation using the accelerated method chosen by the Company.
b. A manual review of each new grant is completed to confirm the accelerated expense method has been applied.
c. Monthly, the Company recalculates a selection from new grants and compares against the stock option expense platform.

In 2023, we completed our remediation activities and found them to be effective. As a result, we have concluded that the material weakness related to share-based compensation has been remediated as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

During the most recently completed fiscal quarter, there have been no material 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.

Item 9B. Other Information

During the year ended December 31, 2023, no Director or Officer of the Company adopted, modified, or terminated a Rule 10b5-1 trading plan.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

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

The information required by this Item will be set forth in our proxy statement for the 2024 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2023, 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 by this Item will be set forth in our proxy statement for the 2024 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2023, and is incorporated herein by reference.

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

The information required by this Item will be set forth in our proxy statement for the 2024 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2023, and is incorporated herein by reference.

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

The information required by this Item will be set forth in our proxy statement for the 2024 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2023, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be set forth in our proxy statement for the 2024 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2023, 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, 2023 and 2022;
    - Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022;
    - Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2023 and 2022;
    - Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022; and
    - 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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated June 12, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 12, 2023).
3.7	Certificate of Designation of Preference, Rights and Limitations of the Series F Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K on March 30, 2023).
3.8	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).

Exhibit No.	Description
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)
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
4.13	Form of Preferred Tranche A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 30, 2023).
4.14	Form of Preferred Tranche B Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 30, 2023).
4.15	Form of Common Tranche A Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report of Form 8-K filed on March 30, 2023).
4.16	Form of Common Tranche B Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on March 30, 2023).
10.2#	Delcath Systems, Inc. 2020 Omnibus Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 13, 2023).
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#	2023 Inducement Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the Commission on December 15, 2023).
10.5#	Form of Inducement Awards Stock Option Award Agreement (incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8 filed with the Commission on December 15, 2023).
10.6#	Form of Off-Plan Inducement Award Stock Option Award Agreement (incorporated by reference to Exhibit 99.4 to the Company's Registration Statement on Form S-8 filed with the Commission on December 15, 2023).
10.7#	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).
10.8#	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).
10.10	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).
10.11	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).
10.12	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).

Exhibit No.	Description
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	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).
10.19	First Amendment to Loan Documents issued by the Company to Avenue Venture Opportunities Fund, L.P., dated March 31, 2023 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed May 22, 2023).
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.
97**	Delcath Systems, Inc., Incentive Compensation Recoupment Policy.
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

Exhibit No.	Description

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 26, 2024

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 26, 2024
/s/ Sandra Pennell Sandra Pennell	Principal Financial and Accounting Officer	March 26, 2024
/s/ John R. Sylvester John R. Sylvester	Chairman of the Board	March 26, 2024
/s/ Elizabeth Czerepak Elizabeth Czerepak	Director	March 26, 2024
/s/ Steven Salamon Steven Salamon	Director	March 26, 2024
/s/ Roger G. Stoll, Ph D Roger G. Stoll, Ph D	Director	March 26, 2024
/s/ Gil Aharon Gil Aharon	Director	March 26, 2024