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, 2025

☐ **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)**

(518) 743-8892
(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 $13.60 per share, as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter was $419,743,586.

On February 13, 2026, the registrant had outstanding 34,746,187 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2026 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, 2025. 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 Annual Report on 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, 2025, 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, 2025 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 (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance, should not be relied upon, 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, 2025 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 expectations and timing related to our ongoing and planned clinical trials evaluating HEPZATO for the treatment of other metastatic cancers;
- our expectations that the results of any current or future clinical trial that we or any collaborator initiates will support increased clinical adoption of and reimbursement for our products;
- our ability to successfully commercialize CHEMOSAT, HEPZATO KIT, and future products, if any, generate additional 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 KIT, and future products, if any;
- the rate and degree of market acceptance and clinical utility of CHEMOSAT, HEPZATO KIT, 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 KIT, and future products, if any, and enter into manufacturing and supplier contracts;
- our ability to source melphalan and other critical components necessary to manufacture HEPZATO KIT;
- our ability to successfully manufacture CHEMOSAT and HEPZATO KIT;
- our ability to comply with applicable requirements, including those associated with the Company's execution of the National Drug Rebate Agreement;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners;
- our estimates of potential market opportunities and our ability to successfully realize these opportunities; and
- contributions to adjusted EBITDA.

Many of the important factors that will determine these results are beyond our ability to control or predict. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our

statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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

- We may need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues may be significantly limited if such capital is then necessary in order to further commercialize CHEMOSAT and HEPZATO, or conduct future product development, including clinical trials, if any.
- We have limited experience as a commercial company and generating revenue from product sales. If the continued commercialization of HEPZATO is unsuccessful or any future approved products are unsuccessful, we may never be profitable or obtain sustainable profitability.
- 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 European Union 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 in the European Union. 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 European Union will be significantly limited.
- We 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 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 and third parties with whom we work are subject to stringent and evolving United States and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to information privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class-action 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.
- 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, and may continue to be volatile and 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 (518) 743-8892 and our internet 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.

Company Overview

We are an interventional oncology company focused on the treatment of cancers primary or metastatic to the liver. Our lead product, the HEPZATO™ KIT (melphalan for Injection/Hepatic Delivery System), a drug/device combination product ("HEPZATO" or "HEPZATO KIT"), 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. The first commercial use of the 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 the HEPZATO KIT to meet anticipated demand and we intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers in the liver. 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 assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

We operate as one operating segment. See Note 16 - "*Segment Information*" in the accompanying notes to our consolidated financial statements for further detail.

Cancers in the Liver—A Significant Unmet Medical Need

According to the American Cancer Society's ("ACS") *Cancer Facts & Figures 2025* report, cancer is the second leading cause of death in the United States, with more than 618,000 deaths and over 2 million new cases expected to be diagnosed in 2025. Cancer is one of the leading causes of death worldwide, accounting for approximately 10 million deaths and 20 million new cases in 2022 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 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.

Cancers in the Liver—Incidence and Mortality

Cancers in the liver consist of primary liver cancer and cancers metastatic to the liver. Primary liver cancers, hepatocellular carcinoma and intrahepatic cholangiocarcinoma, originate in the liver or biliary tract and are 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. We estimate that the total potential addressable market for liver cancer (primary and metastatic) is approximately 200,000 in the United States per year. Based on industry reports, it is estimated the total addressable market ("TAM") in the United States for mUM, metastatic cholangiocarcinoma ("mCCA"), metastatic neuroendocrine tumor ("mNET"), metastatic colorectal cancer ("mCRC"), metastatic breast cancer ("mBC"), metastatic non-small cell lung cancer ("mNSCLC"), metastatic pancreatic cancer ("mPC") and HCC, 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). 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 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 and CHEMOSAT is uniquely positioned either as a standalone therapy or as a complement to other therapies. In clinical studies with HEPZATO 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 or CHEMOSAT annually. Eligible patients are those with limited extrahepatic disease that can be treated with resection or radiation, who are able to safely undergo general anesthesia, and who have metastases involving less than 50% of the liver parenchyma. 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 ("CRC") is one of the most prevalent cancers in the United States and Europe and has a high metastatic rate to the liver. GLOBOCAN 2022 estimates that there are 516,452 CRC diagnoses per year in the United States and the European Union. According to the ACS, in the United States there are approximately 160,186 diagnoses leading to 54,614 deaths.

Recent advances in the treatment of primary CRC 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 ("BC") is the most diagnosed cancer in women in the United States and worldwide. The ACS estimates that 319,750 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 2022 estimates that there are, annually, 708,210 women diagnosed with BC in the United States, the European Union and the United Kingdom. Recent advances in primary

BC treatments have given patients a high 5-year survival rate. The prognosis for patients with BC liver metastasis, however, remains poor.

Approximately 18% of all women diagnosed with BC 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 BC 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 ("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 diagnoses of NETs 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 an aggregate of 7,500 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 ACS 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.

Cholangiocarcinoma

According to GLOBOCAN 2022, an estimated 68,500 new cases of primary liver cancer, or Cholangiocarcinoma ("CCA"), are diagnosed in the United States and Europe annually. According to the ACS, approximately 42,240 new cases of these cancers are expected to be diagnosed in the United States, leading to approximately 30,090 deaths.

Hepatocellular Carcinoma

Hepatocellular Carcinoma ("HCC") is the most common form of primary liver cancer and remains a significant cause of cancer-related mortality globally. According to GLOBOCAN 2022 and updated 2026 projections, there are approximately 110,740 new cases of primary liver cancer diagnosed annually in the United States, the European Union, and the United Kingdom combined. While surgical resection and liver transplantation offer the best hope for a cure, approximately 80% of patients present with unresectable disease at the time of diagnosis or are ineligible for surgery due to underlying cirrhosis or tumor location. For these patients, regional, liver-directed therapies are critical as the disease is inherently confined to the liver parenchyma. We estimate that approximately 65,000 HCC patients annually in the United States and Europe could be candidates for treatments with HEPZATO (if it received FDA approval for such treatment) and CHEMOSAT, representing the largest segment of our addressable primary liver cancer market.

Intrahepatic Cholangiocarcinoma

Intrahepatic Cholangiocarcinoma ("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 may be candidates for certain local treatments. According to third party research that we commissioned, including ICC and extrahepatic liver cancers that have liver involvement, we estimate that approximately 9,000 ICC patients in the United States, the United

Kingdom and the European Union annually could be candidates for treatment with HEPZATO KIT (if it received FDA approval for such treatment) and CHEMOSAT.

Non-small cell lung cancer

Lung cancer is the leading cause of cancer-related death in the United States and Europe, with Non-Small Cell Lung Cancer ("NSCLC") accounting for approximately 85% of all lung cancer diagnoses. We estimate that approximately 240,000 new cases of lung cancer will be diagnosed in the United States annually, with GLOBOCAN 2022 estimating over 640,000 annual diagnoses across the United States, the European Union, and the United Kingdom. While recent advances in systemic immunotherapy and targeted agents have significantly improved 5-year survival rates for mNSCLC, the liver remains a frequent "escape site" for disease progression. Approximately 30% to 40% of patients with mNSCLC will develop liver metastases during the course of their disease, which is often associated with a significantly poorer prognosis and resistance to systemic checkpoint inhibitors. We estimate that a subset of these patients, approximately 34,000 individuals in the United States and Europe annually, present with liver-dominant metastatic disease and could be candidates for treatment with HEPZATO (if it received FDA approval for such treatment) and CHEMOSAT to achieve regional control of their hepatic burden.

About HEPZATO KIT and CHEMOSAT

HEPZATO KIT™ (HEPZATO (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion ("PHP"), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System ("HDS"). In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan. During the PHP procedure the HDS is used to isolate the hepatic venous blood from the systemic circulation while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure.

The PHP procedure is an outpatient procedure performed in an interventional radiology suite in approximately two to three hours. Patients may remain in a post-anesthesia care unit, surgical intensive care unit 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 ten 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 human leukocyte antigen ("HLA") phenotypes or to a specific line of treatment. In Europe, CHEMOSAT is approved for the percutaneous intra-arterial administration of melphalan hydrochloride to the liver, where it has been used in the conduct of percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers to the liver.

The FOCUS Trial

To support the New Drug Application ("NDA") for HEPZATO, we conducted 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 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. On May 6, 2024, we announced the publication of results from our Phase 3 FOCUS Trial, including an ORR of 36.3%, which included 7.7% of patients with Complete Response, as determined by an Independent Review Committee. An ORR of 36.3% in the FOCUS study was statistically significantly better than the pooled ORR estimate (a weighted mean of the observed ORR) of 5.5% in the historical control group. Two additional publications with FOCUS trial results were published, including results from the first, randomized portion of the FOCUS trial (Zager et al., Ann Surg Oncol 2025) and the results from key subgroup analyses of the FOCUS trial (Zager et al., J Cancer Res Clin Oncol 2025). We expect that these publications will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and support reimbursement in various jurisdictions, including the United States.

CHOPIN Trial

The Leiden University Medical Center conducted an investor-initiated Phase 1b/2 trial (the "CHOPIN trial") on the use of CHEMOSAT in combination with the immune checkpoint inhibitors ("ICI") ipilimumab and nivolumab to treat patients with mUM with liver metastases.

The goal of the CHOPIN trial was 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 mUM patients. Ipilimumab and nivolumab are approved by the FDA and European Union for the treatment of unresectable metastatic melanoma. 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.

On October 18, 2025, independent investigators presented results from the Phase 2 portion of the CHOPIN trial. The randomized Phase 2 trial was designed to compare the safety, tolerability, and efficacy of CHEMOSAT with melphalan for percutaneous hepatic perfusion (PHP) when used alone versus when combined with the systemic ICI therapy.

The Phase 2 trial included 76 patients randomized 1:1 to receive two PHP treatments alone at weeks one and seven (PHP group) or four cycles of ICI every three weeks over approximately nine weeks with two PHP treatments at weeks one and seven (combination group). The primary study endpoint of one-year progression-free survival rate was met with 54.7% in the combination group versus 15.8% in the PHP group. The secondary endpoints included Safety, Overall Survival ("OS"), Progression Free Survival ("PFS") and Overall Response Rate ("ORR"). The combination group saw an increase in median OS of 23.1 months versus 19.6 months (HR = 0.39; p = 0.006), median PFS 12.8 months versus 8.3 months (HR = 0.34; p<0.001) and ORR of 76.3% in the combination group versus 39.5% (p<0.001). Grade 3 or higher treatment-related adverse events were more frequent in the combination group (81.6% versus 40.5%, P<0.001), but most were manageable with standard care. The combination treatment adverse events were consistent with the types, rates and frequencies of adverse events in individual use of PHP and checkpoint inhibitors. No new safety signals were identified.

Clinical Development Program

In addition to HEPZATO's FDA approved use to treat mUM, we believe that HEPZATO has the potential to treat other cancers in the liver, such as mCRC, mBC, mCCA, mNET, mNSCLC, mPC and HCC. The focus of our current and planned clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in a broader set of liver cancer indications either as monotherapy or in combination or sequenced with current standard of care therapeutics, including immunotherapy. The ongoing and planned trials may support eventual regulatory submissions for label expansion in the United States as well as support increased clinical adoption and reimbursement in various jurisdictions including the United States and Europe.

We expense research and development costs as they are incurred. We expect our research and development expenses to increase for the foreseeable future relating to the costs required to complete these Phase 2 clinical trials.

Our expected research and development expenses will consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including stock-based compensation;
- fees paid to trial sites, consultants, and the contract research organization (CRO) for the clinical trials, along with other related clinical trial fees, including, but not limited to, clinical trial database management, clinical trial material management and statistical compilation and analysis; and
- costs related to compliance with regulatory requirements.

At this time, we cannot reasonably estimate or know the exact nature, timing and estimated costs of the efforts that will be necessary. Non-refundable advance payments that are made for future research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the services are performed, or when it is no longer expected that the services will be rendered.

Metastatic Colorectal Cancer

Our Investigational New Drug ("IND") application for a Phase 2 clinical trial evaluating HEPZATO in combination with SOC for metastatic breast cancer ("mCRC") was cleared by the FDA in December 2024.

The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with trifluridine-tipiracil and bevacizumab compared to trifluridine-tipiracil and bevacizumab alone in patients with liver-dominant mCRC receiving third-line treatment. Approximately 90 patients will be enrolled in this randomized, controlled trial. Patient enrollment began during the third quarter of 2025, with the study expected to take place at more than 20 sites across the United States and Europe. In July 2025, we received authorization from the European Union and United Kingdom regulatory authorities for the clinical study of Melphalan for Injection/Hepatic Delivery System in patients with refractory metastatic colorectal cancer with the liver dominant disease. The trial's primary endpoint, hepatic progression-free survival ("hPFS"), is anticipated to read out by the end of 2027, while OS, a secondary endpoint, is expected in 2028.

We estimate that the TAM for liver-dominant mCRC receiving third-line treatment is between 6,000 and 10,000 patients annually in the United States. This market includes patients who present with significant liver disease burden, with liver-dominant status determined through radiological and clinical criteria. By targeting this patient population, we aim to provide a novel treatment option for those with limited therapeutic alternatives.

Metastatic Breast Cancer

Our IND application for a Phase 2 clinical trial evaluating HEPZATO in combination with SOC in liver-dominant metastatic breast cancer ("mBC") was cleared by the FDA in April 2025.

The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with SOC versus SOC alone in patients with liver-metastatic HER2-negative mBC following the failure of previous treatments. The SOC options will be the physician's choice of eribulin, vinorelbine or capecitabine. We expect approximately 90 patients will be enrolled in this randomized, controlled trial. The study will take place at more than 15 sites across the United States and Europe, with patient enrollment expected to begin in the first quarter of 2026. The trial's primary endpoint, hPFS, is anticipated to read out by the end of 2028, while results for OS, a secondary endpoint, is expected in 2029.

We estimate that approximately 7,000 patients annually in the United States are affected by HER2-negative metastatic breast cancer with liver metastases and are candidates for third line treatment. This population includes patients with a significant burden of liver metastases, which are likely to be the primary cause of mortality. By focusing on this demographic, we intend to offer a novel therapeutic option to those patients with limited treatment alternatives.

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 treated with HEPZATO or 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 commercial and medical field teams are 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 commercialization. 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, have conducted most of the required training and are actively seeking patient referrals. In addition, www.HEPZATOKITREMS.com contains a healthcare setting locator that lists facilities that have completed and filed all documentation required under REMS. The information found on, or otherwise accessible through, our HEPZATO KIT websites is not incorporated by reference into, and does not form a part of, this Annual Report on Form 10-K.

Upon activation of the cancer center, the center is able to commercially treat patients with HEPZATO. As of December 31, 2025, there were 32 sites accepting referrals, with 25 active sites.

United States Reimbursement

A facility at which HEPZATO is used will seek reimbursement for the cost of the HEPZATO and the attendant procedure. 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 is dependent on the type of health insurance coverage a patient has 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 United States 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.

On January 30, 2024, Centers for Medicare and Medicaid Services ("CMS") announced an established permanent and product-specific J-Code for HEPZATO. The J-Code (J9248) became effective on April 1, 2024. Delcath applied for and was granted transitional drug pass-through status for HEPZATO under the Outpatient Prospective Payment System for hospital outpatient services beginning on April 1, 2024 and expiring on March 31, 2027. On August 5, 2024, CMS announced that it had has granted New Technology Add-on Payment ("NTAP") status for HEPZATO, effective October 1, 2024. The NTAP designation under the CMS Inpatient Prospective Payment System ("IPPS") is designed to support the adoption of innovative medical technologies that provide substantial clinical improvement over existing treatments. HEPZATO is used primarily in the outpatient setting, however there are instances where it is used in the inpatient setting. This additional payment is intended to help to cover the costs associated with HEPZATO for eligible Medicare inpatients, ensuring that more patients can benefit from this advanced liver-directed therapy.

On October 23, 2025, the Company entered into a National Drug Rebate Agreement ("NDRA") with CMS, which also subjected the Company to entering into a Pharmaceutical Pricing Agreement ("PPA") with the Public Health Service and a master agreement with the U.S. Department of Veterans Affairs ("VA"). Pursuant to the NDRA, the Company must pay mandated rebates to states for Medicaid usage. Under the PPA, beginning on July 1, 2025, the Company began selling HEPZATO to eligible covered entities at the statutory 340B price. The Company is also obligated to make any sales to the VA at the Federal Ceiling Price. The NDRA, the PPA, and the agreement with the VA requires the Company to calculate and submit pricing information to the Government and subjects the Company to potential penalties for failing to make timely and/or accurate reports of the required values.

We expect that payors will follow decisions made by the CMS, as the administrator for the Medicare program, regarding HEPZATO reimbursement.

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, we expect that each patient candidate for treatment with HEPZATO will likely have to go through a medical pre-authorization process, which may require the healthcare provider 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, we have

engaged a third-party benefits coordinator to guide the patient and a treating healthcare provider through the pre-authorization and reimbursement process.

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.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, the Inflation Reduction Act ("IRA") among other things, (1) requires the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain single-source biologics that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program (the "Medicare Drug Price Negotiation Program"), and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation on an annual basis. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Europe

Since the launch of CHEMOSAT in Europe, there have been over 2,000 commercial treatments and CHEMOSAT is currently available in 22 cancer centers across Europe. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily uveal melanoma liver metastases, and other tumor types, including hepatocellular carcinoma and cholangiocarcinoma, as well as liver metastases from cutaneous melanoma, colorectal, breast, and pancreatic cancer, as well as neuroendocrine tumors.

For the period of December 2018 through February 2022, medac GmbH was our 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.

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 vary by country. Reimbursement is administered on a regional and national basis. A medical device is typically reimbursed under a Diagnosis Related Groups ("DRG") as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes.

On February 28, 2022, CHEMOSAT received MDR 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 has created the opportunity to apply for National Level reimbursement in each European country for treatment of 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 has an interim level of reimbursement in Germany. Although Delcath submitted an application for CHEMOSAT reimbursement to the NHS in England in January 2025, the application remains pending. In June 2025, CHEMOSAT was approved for reimbursement for two years in the Vastra Gotaland Region in Sweden.

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.

United States 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 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, ("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, ("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 ("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 ("GCP") regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the European Union and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

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

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

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 (“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, (“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 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 an 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 United States Orphan Drug Act (the “ODA”), 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. 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 was approved by the FDA for the designated orphan drug.

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.

United States 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 ("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 healthcare 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 ("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 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 healthcare system and efforts to control healthcare 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 ("ACA"), substantially changed the way healthcare is financed by both governmental and private insurers and has had a significant impact on the pharmaceutical industry.

Since its enactment, there have been amendments and judicial and Congressional challenges and amendments to certain aspects of the ACA.

For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program.

Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. In addition, in December 2025, CMS released two MFN drug pricing proposed rules, which, if adopted would implement mandatory drug rebate schemes for select drugs in Medicare B and Medicare Part D. Other recent actions, for example, include (1) directives to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse ("TrumpRx") for patients to purchase certain products from manufacturers on a cash pay basis; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again ("MAHA") Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan" to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager ("PBM") payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the Inflation Reduction Act ("IRA").

In addition, certain foreign activities related to drugs, biologics, and research, especially with regard to China, have come under increased scrutiny in the United States. On December 10, 2025, the National Defense Authorization Act for Fiscal Year 2026 ("NDAA") passed overwhelmingly in the U.S. House of Representatives (the "House") and includes the BIOSECURE Act which prohibits the U.S. government from procuring biotechnology equipment or services from "biotechnology companies of concern," and would prohibit U.S. government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated "biotechnology company of concern." "Biotechnology companies of concern" include companies identified on the U.S. Department of Defense's "Chinese military companies operating in the United States" list (the 1260H List) and also authorizes the U.S. government to identify additional entities for inclusion as "biotechnology companies of concern". The U.S. Senate passed the NDAA on December 17, 2025 and President Trump subsequently signed the NDAA into law on December 18, 2025. With the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government.

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 European Union plus Norway, Iceland, and Liechtenstein. Under the European Union Medical Device Directive (Directive No 93/42/EEC of 14 June 1993) ("EU MDD"), as last amended, drug delivery

products such as CHEMOSAT are governed by the European Union 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 European Union Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended) ("EUCMPHU"), while the essential requirements of the EU MDD apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the European Union market as a single integral unit with melphalan, the product has been governed solely by the EU MDD, while the separately marketed drug is governed by the EUCMPHU and other European Union legislation applicable to drugs for human use.

In order to commercialize a medical device in the European Union, we must comply with the essential requirements of the EU MDD and more recently, the EU MDR. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the European Union. 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, we 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 MDD 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 MDD. 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 European Union to conduct conformity assessments.

A manufacturer without a registered place of business in a Member State of the European Union that places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by a Competent Authority on the manufacturer's behalf with regard to the manufacturer's obligations under the EU MDD and, more recently, the EU MDR. Our 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 MDD 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 MDR became effective on May 25, 2017, and governs all facets of medical devices.

On February 28, 2022, CHEMOSAT received medical device certification under the EU MDR, which replaced CHEMOSAT's prior certification under the EU MDR. Achieving EU MDR certification entailed a detailed evaluation from a designated European Union Notified Body, including an audit of quality systems and a review of documentation supporting safety and performance claims for the device. The EU MDR greatly expands upon existing EU MDD 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 MDR, CHEMOSAT is a Class III medical device.

In the European Union, 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 European Union must report it to the Competent Authority of the Member State where the incident occurred.

Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action, ("FSCA"). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction.

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.

Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the European Union 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 European Union, the advertising and promotion of our products is also subject to EU Member States laws implementing the EU MDD, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other European Union 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 healthcare professionals.

Failure to comply with the European Union Member State laws implementing the EU MDD and, more recently, the EU MDR, the European Union and European Union Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the European Union 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.

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 healthcare 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 13 United States utility patents, one United States design patent, two pending United States 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, with claims directed to our filter apparatus and media in 15 European countries, and with claims to a kit of parts, directed to CHEMOSAT®, in 18 European countries), three issued foreign counterpart design patents, and two pending foreign counterpart patent applications.

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, United States 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 is 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, as well as potential future conditions, which may be impacted by the implementation of tariffs by the United States and other countries, and new healthcare reforms in the jurisdictions in which we and our suppliers and manufacturers operate 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. Moreover, there is great uncertainty with respect to potential changes in trade regulations, tariffs, sanctions and export controls which also increase volatility in the global economy and may have an adverse impact on our commercial efforts.

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 mUM. 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, and AngioDynamics, Inc. 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.

IDEAYA Biosciences ("IDEAYA") and Replimune Group ("Replimune") are currently developing therapies for the treatment of mUM. IDEAYA is developing darovasertib, an oral protein kinase C PKC inhibitor, in combination with crizotinib, a cMET inhibitor, targeting first-line HLA-A2 negative mUM patients. This combination has received FDA Fast Track designation and is currently being evaluated in a potentially registration-enabling Phase 2/3 trial. In the third quarter of 2025, IDEAYA initiated a global, randomized Phase 3 neoadjuvant registrational trial (designated OptimUM-10) for darovasertib in primary uveal melanoma. Replimune is investigating RP2, an oncolytic immunotherapy, for mUM. Replimune has commenced a randomized Phase 2/3 trial comparing RP2 combined with nivolumab versus the combination of ipilimumab and nivolumab in immune checkpoint inhibitor-naïve adult patients with mUM. Neither of these products have been approved for the treatment of mUM.

Many of our competitors may have substantially greater financial, technological, research and development, marketing, and personnel resources. In addition, some of our competitors may 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 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. 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 20 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 February 13, 2026, including our management team, we had approximately 156 full time employees, of which 141 are located in the United States and 15 are located in Europe. 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. Although we have consolidated our offices to Queensbury, New York, the majority of our employees work remotely outside of the Queensbury area.

As required, we also engage consultants to provide services to us, 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. Our 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 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.

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

We have incurred significant losses since inception and continuing losses may exhaust our capital resources.

As of December 31, 2025, we had $43.5 million in cash and cash equivalents and $47.6 million in short-term investments. We have a substantial accumulated deficit and recurring operating losses in prior years. For the years ended December 31, 2025 and 2024, we incurred a net gain of approximately $2.7 million and a net loss of $26.4 million, respectively, and notwithstanding any prior net gain, we may continue to incur losses in the future. To date, we have funded our operations primarily through a combination of private placements and public offerings of our securities and debt financing, including convertible notes, as well as from revenue we have generated from HEPZATO and CHEMOSAT. 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 potential future losses have had and would continue to have an adverse effect on our stockholders' equity and working capital. Our ability to generate additional product revenue from HEPZATO and CHEMOSAT, for any currently approved indications or any indications for which they are approved in the future, or future product candidates, if any, also depends on a number of additional factors, including, but not limited to, our ability to:

- successfully commercialize and sell HEPZATO and CHEMOSAT pursuant to existing regulatory approvals;
- 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, drug products, and those used to manufacture the medical device, to maintain sufficient supply;
- launch and commercialize any product candidates for which regulatory 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.

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 may need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues may be significantly limited if such capital is then necessary in order 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 the commercialization process, including manufacturing, 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 continue to commercialize HEPZATO in the United States, including expenses related to product sales, marketing, manufacturing and distribution. In the absence of significant revenue from either or both of HEPZATO and CHEMOSAT, we may require substantial additional funding to continue the commercialization of HEPZATO in the United States, 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 ongoing and future clinical trials;
- 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;
- 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.

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, to the extent any outstanding warrants or stock options are exercised, this 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 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. As the result of a dispute, 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 limited experience as a commercial company and generating revenue from product sales. If the continued commercialization 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 in 2024. Our ability to become and remain profitable is heavily dependent on our ability to generate substantial revenue from HEPZATO for the treatment of mUM. The success of our continued 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 continue to 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 continue to 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 European Union 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 and other device components, 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 fail to provide end-users with adequate supplies of melphalan or fail 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 abbreviated NDA holders who have indicated interest in supplying melphalan to us.

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 interruption will not result in a loss of supply in the event an interruption 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, should countries begin to implement changes in trade regulations, tariffs, sanctions and export controls our ability to deliver CHEMOSAT and HEPZATO to purchasers in a timely manner may be adversely impacted and could require us to modify our current supply chain practices, which may impact our product costs, which, if not mitigated, could have a material adverse effect on our business and results of operations.

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 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, or of 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 maintain and, if necessary, expand sales and marketing capabilities and/or enter into agreements with third parties to utilize 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 an effective sales and marketing organization or outsource these functions to other third parties. We have established sales and marketing capabilities to support HEPZATO for the treatment of adult patients with unresectable hepatic-dominant mUM 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 need to enter into collaborative arrangements with third parties to help market and sell CHEMOSAT and HEPZATO, but it may not be successful.

We may be unable to enter into necessary or desired 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. 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. 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;
- natural disasters, 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/UK 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, including such 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 we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in governmental programs that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program (the "MDRP"), as a condition of federal funds being made available for our covered outpatient drugs under Medicaid, we pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we report on a monthly and quarterly basis to the CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, the data includes the Average Manufacturer Price ("AMP") for each drug and, in the case of innovator products, best price. In connection with Medicare Part B, we will continue to submit to Centers for Medicare and Medicaid Services ("CMS") the average sales price ("ASP") on a quarterly basis. ASP is calculated based on a statutorily defined formula, as well as regulations and interpretations of the statute by CMS. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information on a timely basis or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, in which case payment would not be available for our covered outpatient drugs.

In addition, federal law requires that any company that participates in the MDRP also participate in the 340B program. The 340B program is administered by Health Resources & Services Administration ("HRSA") and requires us, as a participating manufacturer, to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. A drug that is designated for a rare disease or condition by the Secretary of HHS is not subject to the 340B ceiling price requirement if the sale is to one of the following types of covered entities: rural referral centers, sole community hospitals, critical access hospitals, and free standing cancer hospitals. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized a revised administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we must also participate in the VA/FSS pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price ("Non-FAMP") for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and states may impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements. If we are found to have violated state law

requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase our costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or undercharge in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price.

We cannot assure that our submissions will not be found to be incomplete or incorrect.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and efforts to control healthcare 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, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to the United States Patient Protection and Affordable Care Act of 2010 ("ACA") marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, United States patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directives to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the MAHA Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan" to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager ("PBM") payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the United States Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

In addition, certain foreign activities related to drugs, biologics, and research, especially with regard to China, have come under increased scrutiny in the United States. For example, on December 18, 2025, President Trump signed the National Defense authorization Act for Fiscal Year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. government from procuring biotechnology equipment or services from "biotechnology companies of concern," and prohibits U.S. government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated "biotechnology company of concern." "Biotechnology companies of concern" include

companies identified on the U.S. Department of Defense's "Chinese military companies operating in the United States" list (the 1260H List) and also authorizes the U.S. government to identify additional entities for inclusion as "biotechnology companies of concern". With the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government.

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 mUM. 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 European Union. 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 European Union will be significantly limited.

In the European Union, 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 European Union.

If physicians are unable or unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the European Union will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the European Union 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 European Union 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 European Union will be significantly limited.

We are subject to significant ongoing regulatory obligations and oversight in the European Union 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, HEPZATO is subject to an extensive REMS program that we must implement and ensure compliance through reporting, auditing and corrective measures. Failure to comply with REMS requirements can result in the imposition of civil monetary penalties, among other things.

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 ODA, 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 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 approvals 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 healthcare 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 (J9248) for HEPZATO, which became 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.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

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 continue to depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. While we believe these products have achieved acceptance to date, there can be no guarantee that the medical community in the United States, European Union or the United Kingdom continue to accept and support the use of CHEMOSAT and HEPZATO in the future. 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 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.

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 healthcare 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 ("HIPAA"). 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 Health Information Technology for Economic and Clinical Health Act ("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;

- the federal transparency requirements under the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS 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, such as Washington's My Health My Data Act, 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 healthcare 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 and the third parties with whom we work are subject to stringent and evolving United States and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to information privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class-action 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 healthcare 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 designed 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). Numerous states have enacted comprehensive 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. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("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 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 with whom we work.

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") impose strict requirements for processing personal data. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million under the EU GDPR, £17.5 million 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 European Union regulations 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 United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the United Kingdom extension thereto (which allows for transfers to relevant United States-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 United Kingdom 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. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

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 statements related to compliance with certain certifications or self-regulatory principles, concerning information privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Our employees and personnel use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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. For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. If we or the third parties with whom we work 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 and imprisonment of company officials. In

particular, plaintiffs have become increasingly more active in bringing privacy-related class-action claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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.

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.

Our patent protection for CHEMOSAT® and HEPZATO® is primarily in the United States, the European Union, and the United Kingdom. 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 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 limited precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC had 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.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Our success depends in part on our ability to commercialize CHEMOSAT and HEPZATO prior to the expiration of our patent protection. 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. In the United States and the European Union, 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. Moreover, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements, and even if we receive an extension, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner.

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. Many of our current and potential competitors have the ability to dedicate substantial resources to challenge our intellectual property rights. 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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. We may be subject to claims by third parties asserting that our licensors, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates.

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 applications filed prior to November 2000 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. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. 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.

Not all of our United States patent rights have corresponding patent rights effective in European or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

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

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

If we breach our license agreements, it could have a material adverse effect on our commercialization efforts for our product candidates.

We have or may in the future license intellectual property rights from third parties. License agreements often impose specified diligence, milestone payment, royalty and other obligations on us and require that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the license agreement. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

We may not have control of the preparation, filing, prosecution, maintenance, enforcement and defense of licensed patents and patent applications. Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are

terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

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. We also employ technical, administrative and physical safeguards designed to restrict proprietary information to authorized personnel and to protect against unauthorized use or disclosure. 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.

Our employees may use generative artificial intelligence (“AI”) technologies in limited and defined circumstances to perform portions of their work. We have implemented an enterprise AI governance framework designed to restrict use, retention, and disclosure of Company data by our employees, directors and service providers within environments controlled by us. Employees are required to complete training and acknowledge our policies governing approved AI usage environments.

Notwithstanding our AI governance framework, public and consumer-grade AI tools provided by third parties may remain technically accessible to employees, directors and service providers, and there can be no assurance these individuals will not inadvertently or improperly use non-approved AI systems or input information that is proprietary, confidential, or sensitive, including trade secrets, into AI platforms in violation of our policies. We monitor compliance with our AI policies through established information security controls however, such controls may not prevent all unauthorized or improper use. In addition, many AI tools are provided by third-party vendors, including vendors with whom we have entered into contractual arrangements governing data handling, and we may have limited ability to control or verify how information submitted outside our approved environments is processed, stored, retained, or used by such providers, including whether such information may be incorporated into model training or otherwise accessed or disclosed.

While we maintain policies, training programs and security controls designed to mitigate these risks, any failure to adequately prevent the disclosure or misuse of our proprietary or confidential information, whether due to employee error, policy non-compliance, inadequate technical controls, evolving AI system functionality, or third-party practices, could result in the loss of trade secret protection and the disclosure of confidential information related to our inventions and

product candidates. Such disclosures could preclude us from obtaining patents covering disclosed inventions and product candidates and could adversely affect our business, competitive position, and operating results.

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 confidentiality, 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 Tax Matters

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. The Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the United States tax laws. For example, effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and required taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The OBBBA restored the tax deductibility of research and development expenses in the year incurred for research activities conducted in the United States for tax years beginning after December 31, 2024. We are evaluating the potential impact that this and other changes under the OBBBA may have on our business. Future guidance from the Internal Revenue Service ("IRS") and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Portions of our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a taxable year is limited to 80% of taxable income in such year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is

generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. In addition, future changes in United States and non-United States tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hoped to achieve by establishing this operational structure. Additionally, taxing authorities, such as the IRS, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such challenge or disagreement were to occur or change in tax law were enacted, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

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 $18.10 on May 19, 2025, and a low of $8.19 on November 20, 2025. 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 or investigations involving us (or our management), 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;
- any trading activity pursuant to a share repurchase program;
- 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, 2025, 34,691,671 shares of common stock are issued and outstanding, and we have reserved 13,943,391 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.

There can be no assurance that any share repurchase will enhance long-term stockholder value.
In November 2025, our Board of Directors authorized a share repurchase program to repurchase up to $25 million of our common stock. We can provide no assurance that any share repurchases will enhance long-term stockholder value, and it may not prove to be the best use of our cash. If our Board of Directors authorizes any additional share repurchase programs it could affect the trading price of our stock and increase volatility.

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. 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 with whom we work 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, or our data, 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 with whom we work collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "Process") 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 with whom we work. 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 with whom we work, 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 with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which are 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 AI, and other similar threats. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks. Remote work 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 (such as our hardware and/or software, including that of third parties with whom we work). It may be

difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. 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. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. For example, we have been the target of unsuccessful phishing attempts in the past and we expect such attempts will continue in the future. While we have contracted with a third party vendor to increase the cybersecurity trainings for all employees there can be no guarantee that future phishing attempts won't be successful.

We have in the past and may in the future 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, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material 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-action 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 material 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.

We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. 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, trade wars, 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 economic environment may continue to be, or become, less favorable than that of past years. Higher costs for goods and services, inflation, deflation, trade tensions, global geopolitical tensions, the imposition of tariffs or other measures that create barriers to or increase the costs associated with international trade, overall economic slowdown or recession and other economic factors in the United States or in any other markets in which we operate could adversely affect our operations and operating results.

The Federal Reserve has raised interest rates multiple times over the past few years 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. Similarly, public health crises and ongoing global geopolitical conflict have at times created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. 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, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly and/or more dilutive.

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

The United States 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 United States lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. The impact of any downgrades to the United States 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 United States 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.

United States 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 Chief Financial Officer ("CFO"), Associate Vice President of Information Technology ("AVPIT") and other IT professionals (together, "IT Team") 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 IT Team identifies and assesses 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 threat actors, subscribing to reports and services that identify cybersecurity threats, evaluating threats reported to us, completing internal and external audits, using external intelligence feeds and completing third-party threat assessments.

We have processes and standards to address cybersecurity matters and mitigate material cybersecurity risk. 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, access controls, identity and access management controls, multi-factor authentication across remote access and cloud-based systems, endpoint protection, malware prevention, disaster recovery and business continuity plans, incident detection and response procedures, and remote access security. All employees are required to complete cybersecurity training at least once a year, and employees also participate in periodic security awareness activities, including simulated phishing exercises, to reinforce cybersecurity best practices.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our AVPIT 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 IT Team has a dedicated staff with combined experience of over 30 years with degrees in Computer Science and Information Science. The IT Team is responsible for reporting on cybersecurity matters to the Board. We support our information security program with external resources including cybersecurity software providers and advisors, as appropriate.

We have a vendor management process to manage cybersecurity risks associated with our use of external providers that includes security reviews conducted prior to onboarding new systems or services, reviews of vendor audits and reports, and contractual obligations related to information security. 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, participates in discussions with senior management and amongst themselves regarding cybersecurity risks. With the assistance of the Company's most senior IT staff, 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 and systems and suppliers and vendors. The oversight from the Board includes material changes to relevant policies, procedures, employee training, and elements of the overall environment, as necessary, and senior management provides updates to the Board regarding emerging cybersecurity threats. The Board has access, as requested, to various reports, summaries or presentations related to cybersecurity, risk and mitigation efforts.

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 mitigate and remediate cybersecurity incidents of which they are notified. The cybersecurity incident

response plan also includes reporting to the Board for certain cybersecurity incidents. Disaster recovery and business continuity plans are reviewed on an ongoing basis and evaluated periodically to support the resiliency of the Company's Information Systems and Data.

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 with whom we work 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, or our data, 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 also own a building comprised of approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York. We lease approximately 18,000 square feet of space at 2 Country Club 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 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 13 - "*Commitment and Contingencies - Litigation, Claims and Assessments - medac Matter*" in the accompanying notes to our consolidated financial statements 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 13, 2026, there were 55 holders of record of our common stock based on information furnished by Equiniti Trust Company, 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.

Recent Sales of Unregistered Securities.

We did not engage in any sales of unregistered securities during the year ended December 31, 2025.

Repurchases of Equity Securities.

On November 19, 2025 our board of directors authorized a share repurchase program under which we may repurchase up to $25 million of our outstanding shares of common stock, from time to time, through open market transactions, privately negotiated transactions or in such other manners approved by the board of directors, in accordance with all applicable securities laws and regulations, including Rule 10b-18 of the Exchange Act. We may enter into a pre-arranged stock trading plan in accordance with the guidelines specified under Rule 10b5-1 to effectuate all or a portion of the share repurchase program. The repurchase program does not obligate us to purchase any shares and does not have an expiration date. The timing and method of any repurchases, which will depend on a variety of factors, including market conditions, are subject to our results of operations, financial condition, liquidity and other factors.

As of the close of trading on December 31, 2025, approximately $19.0 million remained available for repurchase by us under the stock repurchase authorization. The number of shares and average price paid per share for shares repurchased following the authorization of the program in November 2025 are set forth in the table below:

	Total Number of Shares Purchased	Average Price Paid per Share[(1)]	Total Number of Shares Purchased as Part of Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan (in thousands)
Period				
November 1 - 30, 2025	260,000	$9.23	260,000	$ 22,601
December 1 - 31, 2025	368,572	$9.74	368,572	$ 19,012
Total	628,572	$9.53	628,572	

(1) Average price paid per share does not include commission paid or any potential excise tax for share repurchases as part of the Inflation Reduction Act of 2022.

Item 6. [Reserved.]

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

The following discussion of our financial condition and results of operations should be read in conjunction with our 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 cancers primary or metastatic to the liver. Our lead product, the HEPZATO KIT (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. The first commercial use of the HEPZATO KIT for the treatment of 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 the HEPZATO KIT to meet anticipated demand and we intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components.

In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers in the liver. On February 28, 2022, CHEMOSAT received 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.

The FOCUS Trial

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. 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. On May 6, 2024, we announced the publication of results from our Phase 3 FOCUS Trial, including an ORR of 36.3%, which included 7.7% of patients with Complete Response, as determined by an Independent Review Committee. An ORR of 36.3% in the FOCUS study was statistically significantly better than the pooled ORR estimate (a weighted mean of the observed ORR) of 5.5% in the historical control group. We expect that the publication will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and 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 other cancers in the liver, such as metastatic colorectal cancer, metastatic breast cancer, metastatic neuroendocrine tumors and intrahepatic cholangiocarcinoma.

Our IND application for a Phase 2 clinical trial evaluating HEPZATO in combination with SOC for liver-dominant mCRC was cleared by the FDA in December 2024. The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with trifluridine-tipiracil and bevacizumab compared to trifluridine-tipiracil and bevacizumab alone in patients with liver-dominant mCRC receiving third-line treatment. Approximately 90 patients will be enrolled in this randomized, controlled trial. Patient enrollment began during the third quarter of 2025, with the study expected to take place at more than 20 sites across the United States and Europe. In July 2025, we received authorization from the European Union and United Kingdom regulatory authorities for the clinical study of Melphalan for Injection/Hepatic Delivery System in patients with refractory metastatic colorectal cancer with the liver dominant disease. The trial's primary endpoint, hPFS, is anticipated to read out by the end of 2027, while OS, a secondary endpoint, is expected in 2028. We estimate that the total addressable market ("TAM") for liver-dominant mCRC receiving third-line treatment is between 6,000 and 10,000 patients annually in the United States. This market includes patients who present with significant liver disease burden, with liver-dominant status determined through radiological and clinical criteria. By targeting this patient population, we aim to provide a novel treatment option for those with limited therapeutic alternatives.

On April 28, 2025, we announced our IND application clearance by the FDA for the Phase 2 clinical trial of HEPZATO in mBC. The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with SOC versus SOC alone in patients with liver-dominant HER2-negative mBC following the failure of previous treatments. The SOC options will be the physician's choice of eribulin, vinorelbine or capecitabine. We expect approximately 90 patients will be enrolled in this randomized, controlled trial. The study will take place at more than 15 sites across the United States and Europe, with patient enrollment expected to begin in the first quarter of 2026. The trial's primary endpoint, hPFS, is anticipated to read out by the end of 2028, while results for OS, a secondary endpoint, is expected in 2029.

We estimate that approximately 7,000 patients annually in the United States are affected by HER2-negative metastatic breast cancer with liver metastases and are candidates for third line treatment. This population includes patients with a significant burden of liver metastases, which are likely to be the primary cause of mortality. By focusing on this demographic, we intend to offer a novel therapeutic option to those patients with limited treatment alternatives.

We believe that these and similar disease states are areas of unmet medical needs that represent significant market opportunities.

We expense research and development costs as they are incurred. We expect our research and development expenses to increase for the foreseeable future relating to the costs required to complete these Phase 2 clinical trials.

Our expected research and development expenses will consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including stock-based compensation;
- fees paid to trial sites, consultants, and the CRO for the clinical trials, along with other related clinical trial fees, including, but not limited to, clinical trial database management, clinical trial material management and statistical compilation and analysis; and
- costs related to compliance with regulatory requirements.

At this time, we cannot reasonably estimate or know the exact nature, timing and estimated costs of the efforts that will be necessary. Non-refundable advance payments that are made for future research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the services are performed, or when it is no longer expected that the services will be rendered.

The CHOPIN Trial

On October 18, 2025, independent investigators presented results from the Phase 2 CHOPIN clinical trial. The randomized Phase 2 trial was designed to compare the safety, tolerability, and efficacy of CHEMOSAT with melphalan for PHP when used alone versus when combined with the systemic ICIs ipilimumab and nivolumab. Ipilimumab and nivolumab are approved by the FDA and European Union for the treatment of unresectable metastatic melanoma. The CHOPIN trial included 76 patients randomized 1:1 to receive two PHP treatments alone at weeks one and seven (PHP group) or four cycles of ICI every three weeks over approximately nine weeks with two PHP treatments at weeks one and seven (combination group). The primary study endpoint of one-year progression-free survival rate was met with 54.7% in the combination group versus 15.8% in the PHP group. The secondary endpoints included Safety, OS, PFS and ORR. The combination group saw an increase in median OS of 23.1 months versus 19.6 months (HR = 0.39; p = 0.006), median PFS 12.8 months versus 8.3 months (HR = 0.34; p<0.001) and ORR of 76.3% in the combination group versus 39.5% (p<0.001). Grade 3 or higher treatment-related adverse events were more frequent in the combination group (81.6% versus 40.5%, P<0.001), but most were manageable with standard care. The combination treatment adverse events were consistent with the types, rates, and frequencies of adverse events in PHP and checkpoint inhibitors. No new safety signals were identified.

Liquidity and Capital Resources

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Years Ended December 31,	
(in thousands)	2025	2024
Net cash provided by (used in) operating activities	22,516	(18,681)
Net cash used in investing activities	(26,590)	(981)
Net cash provided by financing activities	15,048	39,410
Foreign currency effects on cash	68	(32)
	$ 11,042	$ 19,716

On December 31, 2025, we had cash and cash equivalents totaling $43.5 million and short-term investments totaling $47.6 million, as compared to cash and cash equivalents totaling $32.4 million and short-term investments totaling $20.8 million on December 31, 2024.

We believe that our current cash on hand, cash equivalents and investments will be sufficient to support our current operations through at least 12 months from the issuance of the consolidated financial statements included in this Annual

Report on Form 10-K. Our actual 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; the resolution of any disputes with third parties; and the effect of competing technological and market developments.

Share Repurchase Program

On November 19, 2025, our board of directors authorized a share repurchase program under which we may repurchase up to $25 million of our outstanding shares of common stock, from time to time, through open market transactions, privately negotiated transactions or in such other manners approved by the board of directors. The repurchase program does not obligate us to purchase any shares and does not have an expiration date.

As of December 31, 2025, there have been 628,572 shares of common stock repurchased and retired under the repurchase program at an average price paid per share of $9.5254 for a total aggregate purchase price of approximately $6.0 million. We have approximately $19.0 million remaining under the stock repurchase authorization at December 31, 2025.

Capital Commitments

Our capital commitments over the next twelve months include $11.0 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement. Additional capital commitments beyond the next twelve months include (a) $0.7 million for settlement of litigation with medac and (b) $1.1 million of lease liabilities.

Sources of Liquidity

June 2024 Shelf Registration Statement

On June 28, 2024, we filed a universal shelf registration statement on Form S-3 (the "June 2024 Shelf Registration Statement") with the SEC, pursuant to which we may offer, issue and sell any combination of shares of our common stock, par value $0.01 per share, shares of our preferred stock, par value $0.01 per share, debt securities, warrants to purchase common stock, preferred stock and/or debt securities, in one or more series, and units consisting of any combination of the other types of securities registered under such June 2024 Shelf Registration Statement in an aggregate amount of up to $150 million, in each case, to the public in one or more registered offerings.

Series F Warrants

In May 2020, we completed an underwritten public offering consisting of shares of common stock, Series F warrants to purchase shares of common stock and, to certain investors, in lieu of shares of common stock, pre-funded warrants to purchase shares of common stock. The Series F Warrants had an exercise price of $10.00 per share of common stock and expired on May 5, 2025, while the pre-funded warrants issued in such offering have an exercise price of $0.01, if exercised via cash payment. 1,615,775 Series F Warrants were exercised during the year ended December 31, 2025.

Results of Operations

(In thousands)	Year ended December 31, 2025	2024
Total revenues	$ 85,231	$ 37,205
Cost of goods sold	(11,797)	(6,188)
Gross profit	73,434	31,017
Research and development expenses	29,246	13,874
Selling, general and administrative expenses	43,528	29,553
Total operating expenses	72,774	43,427
Operating income (loss)	660	(12,410)
Interest and other income (expense)	2,850	(13,976)
Income tax expense	810	—
Net income (loss)	$ 2,700	$ (26,386)

Revenue

The increase in total revenue for the year ended December 31, 2025 compared to the same period for 2024 was due to the continued commercial expansion and demand of HEPZATO in the United States and CHEMOSAT in Europe. During the year ended December 31, 2025, 24 sites had treated at least one patient in HEPZATO versus 14 sites in the year ended December 31, 2024.

On October 23, 2025, the Company entered into a National Drug Rebate Agreement ("NDRA") with CMS, which also subjected the Company to entering into a Pharmaceutical Pricing Agreement ("PPA") with the Public Health Service and a master agreement with the U.S. Department of Veterans Affairs ("VA"). Pursuant to the NDRA, the Company must pay mandated rebates to states for Medicaid usage. Under the PPA, beginning on July 1, 2025, the Company began selling HEPZATO to eligible covered entities at the statutory 340B price. The Company is also obligated to make any sales to the VA at the Federal Ceiling Price. See Note 4, *Revenue*, in the accompanying notes to the consolidated financial statements for further details.

Cost of Goods Sold

During the year ended December 31, 2025, we recorded $11.8 million in cost of goods sold. Cost of goods sold increased $5.6 million over the same period in 2024. This increase is directly related to the increase in demand for product revenue which requires an increase in personnel and those associated costs.

Research and Development Expenses

Research and development expenses are incurred for the development of HEPZATO and consist primarily of payroll and payments to contract research and development companies. The increase for the year ended December 31, 2025 compared to the same period in 2024 is due to costs associated with expanding the clinical team including share-based compensation expense related to an increase in headcount and initiation of the Phase 2 clinical trial evaluating HEPZATO in combination with standard of care for mCRC and mBC. In 2024, these costs primarily related to medical affairs and regulatory costs associated with the approved products.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll and professional services such as accounting, legal, marketing and commercial preparation services. For the year ended December 31, 2025 compared to the same period in 2024, selling, general and administrative expenses increased due to continued commercial expansion activities including marketing-related travel expenses and additional personnel on the commercial team. In addition, the increase in personnel along with higher grant date exercise prices has increased the share-based compensation expense.

Interest and other Income/Expense

Interest and other income in 2025 are primarily related to the interest income associated with marketable securities and cash on hand. In 2024, this amount was offset by interest expense related to our debt instruments and the change in fair value of warrant liability. There was no interest expense for the year ended December 31, 2025 due to all debt being paid

off in 2024. There was no change in warrant valuation during the year ended December 31, 2025 due to the exercise of all Tranche B Warrants in 2024.

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 surrounding Significant Accounting Policies can be found in Note 3 to our 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, 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 or decreases in discount rates and the time to payment may result in lower or higher fair value measurements. Increases or decreases in any of those inputs in isolation may result in a significantly lower or higher fair value measurement.

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) and the expected risk-free rate over the expected term (generally estimated by reference to United States treasury instruments with similar remaining terms).

Tax Valuation Allowance

A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized based on the weight of available evidence, both positive and negative. Due to our cumulative loss position and history of operating losses, a full valuation allowance against our net deferred tax assets was considered necessary. We will continue to monitor our cumulative loss position and forecasts and reevaluate the need for a valuation allowance as it could be reversed in future periods.

Accrued Expenses

We utilize CROs 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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

Delcath Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Delcath Systems Inc. (the "Company") as of December 31, 2025, the related consolidated statement of operations and comprehensive income, stockholders' equity and cash flows for the year ended December 31, 2025, 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 as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters 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. We determined that there are no critical audit matters.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2018 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

New York, NY
February 26, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

Delcath Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Delcath Systems Inc. (the "Company") as of December 31 2024, the related consolidated statement of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2024, 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, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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Critical Audit Matters

Critical audit matters 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. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor from 2018 through March 18, 2025.

New York, NY
March 6, 2025

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

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 43,454	$ 32,412
Short-term investments	47,582	20,821
Accounts receivable	11,744	10,890
Inventories	10,252	6,933
Prepaid expenses and other current assets	6,498	2,704
Total current assets	119,530	73,760
Property, plant and equipment, net	3,166	1,790
Right-of-use assets	936	1,039
Total assets	$ 123,632	$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,658	$ 961
Accrued expenses	8,191	5,078
Lease liabilities, current	101	105
Total current liabilities	10,950	6,144
Lease liabilities, non-current	835	933
Other liabilities, non-current	628	766
Total liabilities	12,413	7,843
Commitments and contingencies (see Note 13)		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 14,192 and 14,192 shares issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Common stock, $.01 par value; 80,000,000 shares authorized; 34,691,671 shares and 33,061,002 shares issued and outstanding at December 31, 2025 and 2024, respectively	347	331
Additional paid-in capital	639,145	599,881
Accumulated deficit	(528,848)	(531,548)
Accumulated other comprehensive income	575	82
Total stockholders' equity	111,219	68,746
Total liabilities and stockholders' equity	$ 123,632	$ 76,589

See Accompanying Notes to these Consolidated Financial Statements.

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

	Year ended December 31,	
	2025	**2024**
Product revenue	$ 85,231	$ 37,205
Cost of goods sold	(11,797)	(6,188)
Gross profit	73,434	31,017
Operating expenses:		
Research and development expenses	29,246	13,874
Selling, general and administrative expenses	43,528	29,553
Total operating expenses	72,774	43,427
Operating income (loss)	660	(12,410)
Change in fair value of warrant liability	—	(14,071)
Interest income, net	2,920	125
Other expense	(70)	(30)
Income (loss) before income taxes	3,510	(26,386)
Income tax expense	810	—
Net income (loss)	2,700	(26,386)
Other comprehensive income (loss):		
Unrealized gain on investments adjustments	394	(22)
Foreign currency translation adjustments	99	(31)
Total comprehensive income (loss)	$ 3,193	$ (26,439)
Common share data:		
Basic income (loss) per common share	$ 0.08	$ (0.93)
Weighted average number of basic shares outstanding	35,821,157	28,511,393
Diluted income (loss) per common share	$ 0.07	$ (0.93)
Weighted average number of diluted shares outstanding	39,919,557	28,511,393

See Accompanying Notes to these Consolidated Financial Statements.

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

	Year ended December 31, 2025							
	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	Total
Balance at January 1, 2025	14,192	$ —	33,061,002	$ 331	$ 599,881	$ (531,548)	$ 82	$ 68,746
Compensation expense for issuance of stock options	—	—	—	—	23,971	—	—	23,971
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	261	—	—	261
Issuance of common stock with the Employee Stock Purchase Plan	—	—	58,371	—	481	—	—	481
Warrant Exercise - Series F	—	—	1,615,775	16	16,142	—	—	16,158
Issuance of common stock related to stock option exercises	—	—	585,095	6	4,403	—	—	4,409
Repurchase and retirement of common stock	—	—	(628,572)	(6)	(5,994)	—	—	(6,000)
Net income	—	—	—	—	—	2,700	—	2,700
Unrealized gain on investment adjustments	—	—	—	—	—	—	394	394
Foreign currency translation adjustments	—	—	—	—	—	—	99	99
Balance at December 31, 2025	14,192	$ —	34,691,671	$ 347	$ 639,145	$ (528,848)	$ 575	$ 111,219

See Accompanying Notes to these Consolidated Financial Statements.

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

	Year Ended December 31, 2024							
	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, 2024	24,819	$ —	22,761,554	$ 228	$ 520,576	$ (505,162)	$ 135	$ 15,777
Compensation expense for issuance of stock options	—	—	—	—	9,571	—	—	9,571
Compensation expense for issuance of employee stock option plan	—	—	—	—	196	—	—	196
Private placement - issuance of common stock, net of expenses	—	—	876,627	8	6,763	—	—	6,771
Issuance of common stock with the employee stock purchase plan	—	—	71,558	1	249	—	—	250
Issuance of preferred and common stock related to warrant exercise - F-4 (Tranche B)	2,150	—	3,808,327	38	44,581	—	—	44,619
Issuance of common stock related to warrant exercises - Series E and E-1	—	—	1,045,157	10	16,298	—	—	16,308
Issuance of common stock related to conversion of F-3 Preferred to Common	(11,020)	—	2,448,886	25	(25)	—	—	—
Issuance of common stock related to conversion of F-2 Preferred to Common	(1,457)	—	441,514	4	(4)	—	—	—
Issuance of common stock related to conversion of Series E Preferred to Common	(300)	—	30,000	1	—	—	—	1
Issuance of common stock related to warrant exercise - Pre-funded	—	—	1,307,706	13	(3)	—	—	10
Issuance of common stock related to stock option exercises	—	—	269,673	3	1,679	—	—	1,682
Net loss	—	—	—	—	—	(26,386)	—	(26,386)
Unrealized gain on investments adjustments	—	—	—	—	—	—	(22)	(22)
Foreign currency translation adjustments	—	—	—	—	—	—	(31)	(31)
Balance at December 31, 2024	14,192	$ —	33,061,002	$ 331	$ 599,881	$ (531,548)	$ 82	$ 68,746

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,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ 2,700	$ (26,386)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock option compensation expense	24,232	9,767
Depreciation expense	238	134
Warrant liability fair value adjustment	—	14,071
Amortization of Right-of-Use Asset	111	95
Amortization of debt discount	—	460
Interest expense accrued related to convertible notes	—	133
Interest paid related to convertible notes	—	(847)
Amortization of premiums and discounts on marketable securities	(1,696)	(587)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,421)	(1,639)
Accounts receivable	(854)	(10,649)
Inventory	(3,319)	(3,611)
Accounts payable and accrued expenses	4,766	479
Other liabilities, non-current	(241)	(101)
Net cash provided by (used in) operating activities	22,516	(18,681)
Cash flows from investing activities:		
Purchases of investments	(93,216)	(52,453)
Maturities of investments	68,173	52,031
Purchase of property, plant and equipment	(1,547)	(559)
Net cash used in investing activities	(26,590)	(981)
Cash flows from financing activities:		
Net proceeds from private placement	—	6,771
Proceeds from the issuance of common stock relating to the employee stock purchase plan	481	250
Repayment of Debt	—	(10,610)
Proceeds from the exercise of warrants	16,158	41,317
Proceeds from the exercise of stock options	4,409	1,682
Repurchase and retirement of common stock	(6,000)	—
Net cash provided by financing activities	15,048	39,410
Foreign currency effects on cash	68	(32)
Net increase in total cash	11,042	19,716
Total Cash and Cash Equivalents:		
Beginning of period	32,412	12,696
End of period	$ 43,454	$ 32,412

	Years Ended December 31,	
	2025	**2024**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest paid	$ —	$ 1,236
Taxes paid	$ 1,545	$ —
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right of use assets obtained in exchange for lease obligations	$ —	$ 1,029

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ended December 31, 2025 and 2024

(1) Description of Business

Delcath Systems, Inc. ("Delcath" or "the Company") is an interventional oncology company focused on the treatment of cancers primary or metastatic to the liver. The Company's lead product, the HEPZATO™ KIT (melphalan for Injection/Hepatic Delivery System), a drug/device combination product ("HEPZATO" or "HEPZATO KIT"), 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. The first commercial use of the HEPZATO KIT for the treatment of metastatic uveal melanoma ("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 the HEPZATO KIT to meet anticipated demand and it intends to manage supply chain risk through stockpiled inventory and, where commercially reasonable, contracting with multiple suppliers for critical components.

In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan ("CHEMOSAT"), where it has been used at major medical centers to treat a wide range of cancers in the liver. 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. In June 2025, CHEMOSAT was approved for reimbursement for two years in the Vastra Gotaland Region in Sweden.

On October 18, 2025, the Company announced the results of the investigator-initiated CHOPIN clinical trial. The randomized Phase 2 trial was designed to compare the safety, tolerability, and efficacy of CHEMOSAT with melphalan for percutaneous hepatic perfusion (PHP) when used alone versus when combined with the systemic immune checkpoint inhibitors (ICI) ipilimumab and nivolumab. Ipilimumab and nivolumab are approved by the FDA and European Union for the treatment of unresectable metastatic melanoma. The CHOPIN trial included 76 patients randomized 1:1 to receive two PHP treatments alone at weeks one and seven (PHP group) or four cycles of ICI every three weeks over approximately nine weeks with two PHP treatments at weeks one and seven (combination group). The primary study endpoint of one-year progression-free survival rate was met with 54.7% in the combination group versus 15.8% in the PHP group. The secondary endpoints included Safety, Overall Survival ("OS"), Progression Free Survival ("PFS") and Overall Response Rate ("ORR"). The combination group saw an increase in median OS of 23.1 months versus 19.6 months (HR = 0.39; p = 0.006), median PFS 12.8 months versus 8.3 months (HR = 0.34; p<0.001) and ORR of 76.3% in the combination group versus 39.5% (p<0.001). Grade 3 or higher treatment-related adverse events were more frequent in the combination group (81.6% versus 40.5%, P<0.001), but most were manageable with standard care. Overall, the combination treatment was well tolerated, with types, rates and frequencies of adverse events consistent with individual use of PHP and checkpoint inhibitors. No new safety signals were identified.

To support the New Drug Application for HEPZATO the Company conducted 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. On May 6, 2024, the Company announced the publication of results from the pivotal FOCUS Trial in the journal Annals of Surgical Oncology. In addition, on April 9, 2025, the Company announced the publication of a comparative analysis of the randomized portion of the FOCUS Trial in the Annals of Surgical Oncology. Currently, the Company's clinical development program is

seeking to generate clinical data for CHEMOSAT and HEPZATO either as monotherapy or in combination with immunotherapy. The Company expects 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 other cancers in the liver, such as metastatic colorectal cancer, metastatic breast cancer, metastatic neuroendocrine tumors, and intrahepatic cholangiocarcinoma. The Company believes that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

The Company's investigational new drug application ("IND") for a Phase 2 clinical trial evaluating HEPZATO in combination with standard of care ("SOC") for liver-dominant metastatic colorectal cancer was cleared by the FDA in December 2024. The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with trifluridine-tipiracil and bevacizumab compared to trifluridine-tipiracil and bevacizumab alone in patients with liver-dominant mCRC receiving third-line treatment. Approximately 90 patients will be enrolled in this randomized, controlled trial. Patient enrollment began during the third quarter of 2025, with the study expected to take place at more than 20 sites across the United States and Europe. In July 2025, the Company received authorization from the European Union and United Kingdom regulatory authorities for the clinical study of Melphalan for Injection/Hepatic Delivery System in patients with refractory metastatic colorectal cancer with liver dominant disease.

On April 28, 2025, the Company announced the clearance by the FDA of its IND application for the Phase 2 clinical trial of HEPZATO in liver-dominant metastatic breast cancer. The Phase 2 trial will evaluate the safety and efficacy of HEPZATO in combination with SOC versus SOC alone in patients with liver-dominant HER2-negative mBC following the failure of previous treatments. The SOC options will be the physician's choice of eribulin, vinorelbine or capecitabine. We expect approximately 90 patients will be enrolled in this randomized, controlled trial. The trial will take place at more than 15 sites across the United States and Europe, with patient enrollment expected to begin in the first quarter of 2026.

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.

Factors such as geopolitical events, global health outbreaks, adverse weather events, labor or raw material shortages, imposition of tariffs or trade restrictions and other supply chain disruptions could result in difficulties and delays in manufacturing our products, which could have an adverse impact on our results in operations or result in product shortages, including increasing the cost of ongoing clinical trials. We may also have to take inventory write-offs and incur other charges and expense for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

The United States has announced a broad range of tariffs on goods imported into the United States, many of which were then paused. The majority of the Company's sales are domestic, and while the Company sources certain components outside of the United States, the costs associated with imported materials needed for its operations is a modest portion of our overall manufacturing costs. The Company will continue to monitor the implementation and effect of these and other proposed tariffs.

Liquidity

The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

On December 31, 2025, the Company had cash and cash equivalents totaling $43.5 million and short-term investments totaling $47.6 million.

The Company believes that the current cash on hand, cash equivalents, investments and net cash provided by operating activities will be sufficient to support current operations through at least 12 months from the issuance of these condensed consolidated financial statements. Actual 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; the resolution of any disputes with third parties; and the effect of competing technological and market developments.

(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.

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). At December 31, 2025, all investments held by the Company had remaining contractual maturities of less than six months.

Accounts Receivable

Accounts receivable, principally trade, are generally due within 30 to 60 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.

The following table shows the opening and closing balances for the years ended:

(in thousands)	December 31, 2025	December 31, 2024
Opening Balance	$ 10,890	$ 241
Closing Balance	$ 11,744	$ 10,890

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. Revenue is recognized when or as the Company transfers control of the promised goods to its customers in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods.

The Company does not currently have any but 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 judgments and estimates involve the determination of variable consideration to be included in the transaction price, including rebates that may be due under the Medicaid Drug Rebate Agreement. 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.

As required by ASC 606, the Company disaggregates its revenue into the categories of product revenue and other revenue. In 2025, the Company recognized only product revenue. See Note 4, *Revenue*, in the accompanying notes to the consolidated financial statements for further detail.

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 three years for grants to employees and one year for grants to non-employee directors and is generally also the vesting period of the equity grant. The Company accounts for forfeitures as they occur. 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. The exercise price is greater than or equal to the fair market value of the common stock at the date of the grant and 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 14 - *Income Taxes* for additional information.

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 February 26, 2026, which is the date the consolidated financial statements were issued, determining all subsequent events have been disclosed.

Recently Issued Accounting Pronouncements

ASU 2024-03, Disaggregation of Income Statement Expenses

In November 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-03, Income Statement - Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures to improve the disclosures about a public entity's expenses and provide more detailed information about the types of expenses in commonly presented expense captions such as inventory purchases, employee compensation, depreciation and intangible asset amortization. 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, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

Recently Adopted Accounting Pronouncements

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 are effective for annual periods beginning after December 15, 2024. The guidance is applied on a prospective basis with the option to apply the standard retrospectively. The Company adopted ASU 2023-09 on a prospective basis beginning with the year ended December 31, 2025. See Note 14 - *Income Taxes* in the accompanying notes to the consolidated financial statements for further detail.

(4) Revenue

The Company recognizes product revenue from sales of HEPZATO in the United States and CHEMOSAT in certain European countries in accordance with the five-step model in Accounting Standards Codification (ASC) 606, Revenue Recognition: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation. Under this revenue standard, the Company recognizes revenue when its customer obtains control of the promised goods, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods.

Payment terms, returns, and warranties

The Company's revenue arrangements do not contain significant financing components as payment terms are generally 30 to 60 days. HEPZATO and CHEMOSAT have no contractual rights of returns, refunds or similar obligations beyond assurance-type quality warranties. HEPZATO or CHEMOSAT kits that are deemed defective are replaced at no cost to the hospital or treating center.

The Company does not have any contract assets or contract liabilities at December 31, 2025 or 2024 because the contracts generally do not include performance obligations satisfied over time or advance customer consideration.

HEPZATO

The Company ships and sells HEPZATO directly to hospitals and treating centers based on approved agreements. For certain customers, the inventory is considered on consignment in which the Company retains title to the product until the use of the HEPZATO. For these sales, the Company recognizes HEPZATO revenue, based on contracted or published rates, upon completion of the procedure. There is no obligation for the hospitals or treating centers to use the consigned HEPZATO, and the Company has no contractual right to receive payment until the product is used in a procedure and transfer of control is completed. See Note 6 - *Inventories* for further information regarding consignment inventory.

Hospitals and treating centers may also elect to purchase HEPZATO prior to a procedure. For these sales, the purchasing hospital or treatment center obtains control of the product once it is delivered. In these instances, the Company recognizes revenue based on contracted rates stated in an approved contract or purchase order upon delivery to the customer.

On May 22, 2025, the Company announced a plan to enter into a National Drug Rebate Agreement ("NDRA") with the Centers for Medicare and Medicaid Services ("CMS"), which also subjected the Company to entering into a Pharmaceutical Pricing Agreement ("PPA") with the Public Health Service and a master agreement with the U.S. Department of Veterans Affairs ("VA"). Pursuant to the NDRA, the Company must pay mandated rebates to states for Medicaid usage. The rebates are variable consideration and must be estimated at each reporting period and are treated as a reduction of revenue in the same period the related revenue is recognized. These estimates are based on historical experience and payer mix and will be adjusted as actual claims are processed. At December 31, 2025, there were no accrued rebates included in the Company's financials.

Under the PPA, beginning on July 1, 2025, the Company began selling HEPZATO to eligible covered entities at the statutory 340B price. The Company is also obligated to make any sales to the VA at the Federal Ceiling Price. Due to the Company selling directly to the hospital or treating center, the purchase price of either wholesale acquisition cost or 340B is known at the time of revenue recognition. No chargeback estimate is recorded on the consolidated balance sheets.

The NDRA, the PPA, and the agreement with the VA requires the Company to calculate and submit additional pricing calculations and subject the Company to potential penalties for failing to make timely and/or accurate reports of the required values.

CHEMOSAT

CHEMOSAT is sold directly to hospitals in the European Union and United Kingdom based on contracted rates in an approved contract or sales order. The Company recognizes product revenue from sales of CHEMOSAT upon shipment.

Revenue by product for the periods indicated were as follows:

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ended December 31, 2025 and 2024
(amounts in thousands, except share and per share amounts)

(In thousands)	Twelve Months Ended December 31, 2025	2024
CHEMOSAT	$ 6,396	$ 4,902
HEPZATO KIT	78,835	32,303
Total revenue	$ 85,231	$ 37,205

Concentration of Credit Risk

Potential credit risk exposure for both the HEPZATO KIT and CHEMOSAT has been evaluated for the Company's accounts receivable in accordance with ASC 326, Financial Instruments - Credit Losses. The loss percentage is calculated through the use of current and historical economic and financial information. As of December 31, 2025, there were no estimated losses applied to the accounts receivables balance.

The Company's total percentage of revenue and accounts receivable balances were comprised of the following concentrations from its largest customers, based on whose revenue or accounts receivable concentration is greater than 10% of total revenue or total accounts receivable in the periods disclosed below.

For the twelve months ended and as of December 31, 2025	% of Revenue	% of Accounts Receivable
Customer 1	15.2 %	24.0 %

For the twelve months ended and as of December 31, 2024	% of Revenue	% of Accounts Receivable
Customer 1	20.1 %	10.1 %
Customer 2	17.7 %	30.2 %
Customer 3	13.2 %	3.4 %
Customer 4	11.3 %	16.8 %

(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 consolidated balance sheets.

The following table summarizes the gross unrealized gains on the Company's marketable securities as of December 31, 2025:

	December 31, 2025		
		Gross Unrealized	
(In thousands)	Amortized Cost	Gains	Estimated Fair Value
U.S. government agency bonds	$ 47,053	$ 529	$ 47,582
Classified as:			
Short-term investments			$ 47,582

As of December 31, 2025, there was $0.5 million of interest receivable related to the outstanding debt securities held by the Company.

The following table summarizes the gross unrealized gains on the Company's marketable securities as of December 31, 2024:

	December 31, 2024		
		Gross Unrealized	
(In thousands)	Amortized Cost	Gains	Estimated Fair Value
U.S. government agency bonds	$ 20,686	$ 135	$ 20,821
Classified as:			
Short-term investments			$ 20,821

As of December 31, 2024, there was $0.1 million of interest receivable related to the outstanding debt securities held by the Company.

(6) Inventory

Inventory consists of the following:

(In thousands)	December 31, 2025	December 31, 2024
Raw materials	$ 6,477	$ 3,849
Work-in-process	2,809	2,260
Finished goods	966	824
Total inventories	$ 10,252	$ 6,933

The Company has consignment agreements with approved hospitals and treatment centers. As of December 31, 2025, there was approximately $0.6 million in finished goods held at hospitals and treatment centers.

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(7) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(In thousands)	December 31, 2025	December 31, 2024
Clinical trial expenses	$ 2,405	$ 222
Insurance premiums	547	161
Professional services	804	762
Interest receivable	499	125
Licenses	613	990
Software	706	164
Taxes	696	45
Other	228	235
Total prepaid expenses and other current assets	$ 6,498	$ 2,704

(8) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(In thousands)	December 31, 2025	December 31, 2024	Estimated Useful Life
Buildings and land	$ 1,557	$ 1,318	30 years - Buildings 15 years - Land Improvements
Enterprise hardware and software	1,819	1,811	3 years
Leaseholds	1,648	1,585	Lesser of lease term or estimated useful life
Equipment	2,894	1,671	7 years
Furniture	251	232	5 years
Equipment in process	245	127	
Property, plant and equipment, gross	8,414	6,744	
Accumulated depreciation	(5,248)	(4,954)	
Property, plant and equipment, net	$ 3,166	$ 1,790	

Depreciation expense for the years ended December 31, 2025 and 2024 was $0.2 million and $0.1 million, respectively.

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(9) Accrued Expenses

Current accrued expenses include the following:

(In thousands)	December 31, 2025	December 31, 2024
Clinical expenses	$ 2,065	$ 615
Compensation, excluding taxes	4,248	3,471
ESPP withholding	396	240
Professional fees	736	57
Inventory	74	44
medac	235	208
Other	437	443
Total accrued expenses	$ 8,191	$ 5,078

(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.

For both the years ended December 31, 2025 and 2024, the Company recognized $0.2 million of operating lease expense and $0.1 million was recorded for short-term leases.

In 2021, 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 annual rent expense under the 2021 Sub-Lease is less than $0.1 million for a term of 5 years.

On January 18, 2024, 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 five years with a right to extend the lease by an additional five years, exercisable under certain conditions set forth in the Queensbury Lease. The Company's annual rent expense under the Queensbury Lease is less than $0.2 million for a term of 5 years.

The following table summarizes the Company's operating leases as of December 31, 2025:

(In thousands)	U.S.	Ireland	Total
Operating cash flows from operating leases	$ (144)	$ (46)	$ (190)
Weighted average remaining lease term	8.1	0.6	
Weighted average discount rate - operating leases	8%	8%	

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

(In thousands)	U.S.	Ireland	Total
Year ended December 31, 2026	$ 144	$ 27	$ 171
Year ended December 31, 2027	148	—	148
Year ended December 31, 2028	152	—	152
Year ended December 31, 2029	157	—	157
Year ended December 31, 2030	158	—	158
Thereafter	486	—	486
Total	1,245	27	1,272
Less present value discount	(335)	(1)	(336)
Operating lease liabilities included in the consolidated balance sheets at December 31, 2025	$ 910	$ 26	$ 936

(11) Stockholders' Equity

Public and Private Placements

June 2024 Shelf Registration Statement

On June 28, 2024, the Company filed a universal shelf registration statement on Form S-3 (the "June 2024 Shelf Registration Statement") with the SEC, pursuant to which the Company may offer, issue and sell any combination of shares of the Company's common stock, par value $0.01 per share, shares of the Company's preferred stock, par value $0.01 per share, debt securities, warrants to purchase common stock, preferred stock and/or debt securities, in one or more series, and units consisting of any combination of the other types of securities registered under such June 2024 Shelf Registration Statement in an aggregate amount of up to $150 million, in each case, to the public in one or more registered offerings. The June 2024 Shelf Registration Statement was declared effective on August 5, 2024.

Authorized 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, 2025, the Company has designated the following preferred stock:

Designated Preferred Shares	December 31, 2025
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, 2025, there were an aggregate of 10,957 shares of Series E and Series E-1, 1,085 Series F-2, and 2,150 Series F-4 Convertible Preferred Stock outstanding, respectively.

Subject to limitations set forth in the Beneficial Ownership Limitation, the shares of Series E and E-1 Preferred Stock are convertible into common stock at the option of the holder at the conversion price of $10.00 per share.

Subject to limitations set forth in the Certificate of Designation, the shares of Series F-2 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 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.

Share Repurchase Program

On November 19, 2025 the Company's Board of Directors authorized a share repurchase program under which the Company may repurchase up to $25 million of its outstanding shares of common stock, from time to time, through open market transactions, privately negotiated transactions or in such other manners approved by the Board of Directors, in accordance with all applicable securities laws and regulations, including Rule 10b-18 of the Exchange Act. The Company may enter into a pre-arranged stock trading plan in accordance with the guidelines specified under Rule 10b5-1 to effectuate all or a portion of the share repurchase program. The repurchase program does not obligate the Company to purchase any shares and does not have an expiration date. The timing and method of any repurchases, which will depend on a variety of factors, including market conditions, are subject to our results of operations, financial condition, liquidity and other factors.

As of December 31, 2025, there have been 628,572 shares of common stock repurchased and retired under the repurchase program at an average price paid per share of $9.5254 for a total aggregate purchase price of approximately $6.0 million. The Company had approximately $19.0 million remaining under the stock repurchase authorization at December 31, 2025.

Omnibus Equity Incentive Plan

On September 30, 2020, the Company's 2020 Omnibus Equity Incentive Plan (the "2020 Plan") was adopted by the Company's Board of Directors. On November 23, 2020, the Company's stockholders approved the 2020 Plan. The 2020 Plan will continue in effect until the tenth anniversary of the date of its adoption by the Board or until earlier terminated by the Board. The 2020 Plan is administered by the Board of Directors or a committee designated by the Board of Directors. The 2020 Plan provides for the grant of 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, 2025, there have been 9,325,000 shares of common stock reserved under the 2020 Plan, which includes an additional 2,200,000 shares approved by shareholders on May 15, 2025, of which 2,470,507 remained available to be issued as of December 31, 2025 under the 2020 Plan.

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.

Inducement 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

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

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, 2025, there have been 1,100,000 shares of common stock reserved under the 2023 Plan, of which 174,586 remain available to be granted.

Stock Options

The following table sets forth information as of December 31, 2025 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	6,051,897	$ 9.97	2,470,507
Equity compensation plans not approved by security holders [(1)]	1,733,252	$ 10.36	174,586
Total	7,785,149	$ 10.05	2,645,093

(1) Includes (a) stock options for an aggregate of 142 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 1,235,110 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 57 employees hired between 2022 and 2025.

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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 assumption ranges for new grants during the reporting periods:

	Years Ended December 31	
	2025	2024
Expected terms (years)	5.2 - 5.9	5.2 - 5.9
Expected volatility	75.6% -90.1%	98.3.% - 128.6%
Risk-free interest rate	3.8% - 4.4%	3.7% - 4.7%
Expected dividends	0.00%	0.00%

The following is a summary of stock option activity for the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2025	5,766,927	$ 7.23	7.5	$ 28,796
Granted	2,772,663	15.49	9.1	
Exercised	(585,095)	7.54		
Expired	(65,761)	12.97		$ 1
Cancelled/Forfeited	(103,585)	10.63		$ 461
Outstanding at December 31, 2025	7,785,149	$ 10.05	7.8	$ 17,391
Exercisable at December 31, 2025	4,856,441	$ 8.77	7.1	$ 13,051
Unvested at December 31, 2025	2,928,708	$ 12.19	8.8	$ 4,339

The weighted average grant-date fair value of the stock options granted during the years ended December 31, 2025 and 2024 was approximately $11.60 and $4.29 per share, respectively. The aggregate intrinsic value of stock options exercised was $3.0 million and $1.0 million for the years ended December 31, 2025 and December 31, 2024, respectively. Total cash received as a result of stock option exercises was $4.4 million and $1.7 million for the years ended December 31, 2025 and December 31, 2024, respectively. Upon exercise, new shares are issued from authorized and unissued shares.

The following is a summary of share-based compensation expense in the statement of operations for the twelve months ended December 31, 2025 and December 31, 2024:

	Year Ended December 31,	
(In thousands)	2025	2024
Selling, general and administrative	$ 15,556	$ 6,690
Research and development	6,281	2,286
Cost of goods sold	2,395	791
Total	$ 24,232	$ 9,767

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

At December 31, 2025, there was approximately $12.0 million of aggregate unrecognized compensation expense related to employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 0.9 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 560,295 shares of common stock to be purchased by participating employees, which includes an additional 300,000 shares approved by shareholders on May 15, 2025, of which 171,364 have been issued as of December 31, 2025 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.

Common Stock Warrants

The following is a summary of common stock warrant activity for the year ended December 31, 2025:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2025	3,193,275	$ 5.80
Warrants issued	—	—
Warrants exercised	(1,615,775)	10.00
Warrants cancelled	(236,125)	10.00
Outstanding and exercisable at December 31, 2025	1,341,375	$ 0.01

The following table presents information related to common stock warrants at December 31, 2025:

	Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)
$0.01 (1)	1,341,375	n/a

(1) Pre-funded warrants with a $0.01 exercise price do not expire until exercised.

(12) Net Income (Loss) Per Share

Basic net income (loss) per share is determined by dividing net income (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 income (loss) per share is determined by dividing net income (loss) by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options, stock purchased pursuant to the Company's employee stock purchase plan, convertible notes and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

At both December 31, 2025 and 2024, the Company had 1,341,375 pre-funded warrants outstanding. The following tables provides a reconciliation of the weighted average shares outstanding calculation for the year-ended December 31, 2025 and 2024.

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

Weighted average number of basic shares outstanding

	Year ended December 31,	
	2025	**2024**
Weighted average shares issued	34,479,782	27,571,541
Weighted average pre-funded warrants	1,341,375	939,852
Weighted average shares outstanding	35,821,157	28,511,393

Weighted average number of diluted shares outstanding

	Year ended December 31,	
	2025	**2024**
Weighted average shares outstanding (Basic)	35,821,157	28,511,393
Additional dilutive shares	4,098,400	—
Weighted average shares outstanding (Diluted)	39,919,557	28,511,393

For the years ended December 31, 2025 and 2024 the following potentially dilutive securities were excluded from the computation of diluted earnings per share because their effects would be antidilutive:

	December 31,	
	2025	**2024**
Common stock warrants - equity	—	1,851,900
Assumed conversion of preferred stock	—	1,782,842
Stock options	3,845,762	5,766,927
Assumed conversion of ESPP shares	47,815	35,513
Total	3,893,577	9,437,182

(13) 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. Annual payments were made in May 2024 and 2025. The Company has estimated the remaining fair value of the settlement to be $0.9 million as of December 31, 2025 and recorded $0.6 million as other liabilities, non-current and $0.3 million as accrued expenses

on the Company's consolidated balance sheet as of December 31, 2025. See Note 15 - *Fair Value Measurements* in our consolidated financial statements for further detail.

Manufacturing and Supply Agreements

The Company has a License, Supply and Contract Manufacturing Agreement (as amended, the "Supply Agreement") with Synerx Pharma, LLC and Mylan Teoranta for the supply of melphalan provided in the HEPZATO KIT. An amendment to the Supply Agreement was entered into on April 22, 2024, and effective as of May 1, 2024, which extends the term of the agreement through December 31, 2028, with an option to extend its term for five-year periods upon the mutual written consent of both parties. Although the Supply Agreement does not contain an annual minimum purchase quantity, the Agreement requires Delcath to order full lots of labeled melphalan vials. As of December 31, 2025, the Company has committed to purchase $2.5 million of melphalan under this Supply Agreement in 2026.

Agreements Relating to Clinical Trial Support

The Company has engaged Precision for Medicine LLC ("PfM") a Clinical Research Organization ("CRO") to support the Company's Phase 2 clinical trials evaluating HEPZATO in combination with standard of care in patients with liver dominant mCRC and HER2-negative mBC. In addition to the CRO engagement, the Company has also contracted with other vendors, including those relating to data management as well as clinical trial sites as the studies progress. Deposits totaling $2.3 million have been made by the Company in connection with these engagements that are to be applied to future payments due under the service agreements.

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(14) Income Taxes

The components of income tax provision (benefit) for the years ended December 31, 2025 and 2024 were as follows:

	For the Year Ended December 31,	
(In thousands)	**2025**	**2024**
Current provision		
Federal	$ 12	$ —
State	748	—
Foreign	50	—
Total current provision	$ 810	$ —
Deferred provision		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total deferred provision	$ —	$ —
Total provision (benefit) for income taxes	$ 810	$ —

Income (loss) before income taxes consists of:

	For the Year Ended December 31,	
(In thousands)	**2025**	**2024**
Domestic	$ 2,720	$ (26,806)
Foreign	790	420
Income before taxes	$ 3,510	$ (26,386)

The Company adopted ASU 2023-09 "Income Taxes (Topic 740): Improvements To Income Tax Disclosures" on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax amount and rate to our actual global effective amount and rate for the year ended December 31, 2025:

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(In thousands)	For the Year Ended December 31, 2025 Amount	Percentage
U.S. federal statutory tax rate	735	20.9 %
State and local income taxes, net of federal income tax effect (1)	591	16.8 %
Foreign tax effects		
Ireland		
Statutory tax rate difference between Ireland and the United States	(79)	(2.3)%
Changes in valuation allowances	157	4.5 %
Provision to return	(236)	(6.7)%
Nondeductible expenses	(37)	(1.1)%
United Kingdom		
Statutory tax rate difference between United Kingdom and the United States	(5)	(0.1)%
Changes in valuation allowances	—	— %
Provision to return	—	— %
Nondeductible expenses	50	1.4 %
Germany		
Statutory tax rate difference between Germany and the United States	(4)	(0.1)%
Changes in valuation allowances	—	— %
Provision to return	—	— %
Nondeductible expenses	45	1.3 %
Other countries	(7)	(0.2)%
Effect of changes in tax laws or rates enacted in the current period	—	— %
Effect of cross-border tax laws		
Global intangible low-taxed income	52	1.5 %
Foreign disregarded entity branch inclusion	195	5.6 %
Tax credits		
Research and development tax credits	(1,180)	33.6 %
Changes in valuation allowances	(3,275)	93.3 %
Nontaxable or nondeductible items		
Stock compensation	3,694	105.2 %
Meals and entertainment	43	1.2 %
Other	16	0.5 %
Changes in unrecognized tax benefits	—	— %
Other adjustments	55	1.6 %
Provision for income taxes and effective tax rate	810	23.1 %

(1) During the year ended December 31, 2025, state taxes in Pennsylvania and California made up the majority of tax effects in this category.

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The following table presents the required disclosures prior to the adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to the actual global effective income tax rate for the year ended December 31, 2024:

(In thousands)	For the Year Ended December 31, 2024
Income taxes using U.S federal statutory rate	$ (5,541)
Nondeductible interest	64
Branch income	151
State income taxes, net of federal benefit	(1,513)
Foreign rate differential	(67)
Valuation allowance	3,029
Stock option expense, exercises and cancellations	1,336
Research and development costs	(746)
Other	332
Derivative Charge	2,955
	$ —

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

	For the Year Ended December 31,	
(In thousands)	**2025**	**2024**
Deferred tax assets:		
Employee compensation accruals	$ 3,196	$ 2,182
Accrued liabilities	892	707
Research tax credits	4,231	3,015
Lease obligation	225	249
Other	151	171
Research expense capitalization	1,305	6,927
Net operating losses	28,354	29,071
Total deferred tax assets	$ 38,354	$ 42,322

	For the Year Ended December 31,	
(In thousands)	**2025**	**2024**
Deferred tax liabilities:		
Right of use asset	$ 225	$ 249
Total deferred tax liabilities	225	249
Valuation allowance	38,129	42,073
Net deferred tax assets	$ —	$ —

As of December 31, 2025, and 2024, the Company had net operating loss carryforwards for United States federal income tax purposes of approximately $295.7 million and $301.1 million, respectively. A significant portion of the federal amount is subject to an annual limitation as low as $28 thousand 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 $194.6 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $101.1 million of net operating loss carryforwards remains available to offset future federal taxable income, of which $1.5 million will expire between 2025 and 2037 and $99.6 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, 2025, and 2024, the Company had net operating loss carryforwards for states and city income tax purposes between approximately $0.1 million and $200.2 million and between approximately $0.6 million and $200.2 million, respectively, which expire through 2044. As a result of the Section 382 limitations, approximately $191.1 million and $175.3 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $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, 2025 and 2024, the Company had a net operating loss carryforward for foreign income tax purposes of $47.0 million and $40.3 million, respectively, which have indefinite carryforward periods. As of December 31, 2025 and 2024, the Company had federal research and development tax credit carryforwards of approximately $9.2 million and $8.1 million, respectively, which expire through 2045. As a result of the Section 382 limitations, all but $4.1 million of the tax credit carryforwards is expected to expire unutilized.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company's valuation allowance decreased by approximately $3.9 million and increased by $2.8 million in 2025 and 2024, respectively. The change in valuation allowance is as follows:

	December 31,	
(In thousands)	2025	2024
Beginning Balance	$ 42,073	$ 39,301
Charged to costs and expenses	(4,491)	3,028
Charged to other comprehensive income	547	(256)
Ending balance	$ 38,129	$ 42,073

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, 2022; tax years ending December 31, 2022 through December 31, 2025 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, 2020 (as Ireland has not initiated an audit of 2019 as of December 31, 2025); tax years ending December 31, 2020 through December 31, 2025 remain open to examination. However, the Company's tax years December 31, 1998 through

December 31, 2025 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, 2025.

The Company adopted ASU 2023-09 on a prospective basis for the year ended December 31, 2025 and has included the following table as a result of adoption, which presents income taxes paid (net of refunds received) for the year ended December 31, 2025:

(In thousands)	For the Year Ended December 31, 2025
U.S. Federal	$ 741
State:	
California	331
Massachusetts	98
Pennsylvania	207
Other states	118
State subtotal	754
Foreign:	
Other countries	50
Foreign subtotal	50
Total cash paid for income taxes (net of refunds)	$ 1,545

The Company had no income taxes paid for the year ended December 31, 2024, prior to the adoption of ASU 2023-09.

One Big Beautiful Bill

On July 4, 2025, President Trump signed into law the One Big Beautiful Bill Act ("OBBBA"), which resulted in the extension of many provisions of the current tax law as well as other rule changes that could impact the Company's tax provision in 2025 or 2026. Examples of the new tax law include the following:

- Full expensing of U.S. research and development costs under Section 174A.
- Retroactive expensing of unamortized U.S. research and development costs capitalized between 2022 and 2024; either all in 2025, or over two years in 2025 and 2026.
- Return of the Section 163(j) taxable income base excluding the deductions for depreciation and amortization in 2025 (change from "Tax EBIT" to "Tax EBITDA").

- Decrease in the Section 250 deduction for Net CFC Tested Income (formerly GILTI) to 40% (from 50%) in 2026, instead of the scheduled decrease to 37.5% prior to the OBBBA.
- Decrease in the Section 250 deduction for foreign-derived income to 33.34% (from 37.5%) in 2026, instead of the scheduled decrease to 21.875% prior to the OBBBA.
- Increase in the foreign tax credit rate on Net CFC Tested Income (formerly GILTI) to 90% (from 80%), and a 10% disallowance on repatriation, in 2026.
- Removal of the allocation of interest expense and research and development expense to Net CFC Tested Income (formerly GILTI) in calculating the foreign tax credit limitation, effective in 2026.

The Company's tax provision of $810 thousand for the year ended December 31, 2025 is predominantly related to $748 thousand of state income taxes in jurisdictions which do not conform to the retroactive expensing of unamortized United States research and development costs capitalized between 2022 and 2024. As the Company records a full valuation on deferred tax assets, there is no deferred tax provision recorded as a results of the OBBBA.

(15) 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, 2025:

	Level 3
(In thousands)	Contingent Liabilities
Balance at January 1, 2025	$ 974
Change due to liability payment	(208)
Liability fair value adjustment	(4)
Total change in foreign exchange	102
Balance at December 31, 2025	$ 864

Contingent liabilities are re-measured to fair value each reporting period using projected financial targets, discount rates, probabilities of payment, and projected payment dates.

Significant unobservable inputs in the valuation include:

- Probability of payment: 100%
- Discount rate: 3.75%
- Timing of expected payments: 0 - 2 years

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 immaterially lower or higher fair value measurement.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of December 31, 2025 and December 31, 2024 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value.

	December 31, 2025			
(In thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 2	$ —	$ —	$ 2
U.S. government agency bonds		47,582	—	47,582
Total Assets	$ 2.00	$ 47,582	$ —	$ 47,584
Liabilities:				
Contingent Liability	$ —	$ —	$ 864	$ 864
Total Liabilities	$ —	$ —	$ 864	$ 864

	December 31, 2024			
(In thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 9	$ —	$ —	$ 9
U.S. government agency bonds	—	20,821	—	20,821
Total Assets	$ 9	$ 20,821	$ —	$ 20,830
Liabilities:				
Contingent Liability	$ —	$ —	$ 974	$ 974
Total Liabilities	$ —	$ —	$ 974	$ 974

(16) Segment Information

The Company operates its business primarily in the United States and Europe on a consolidated basis in one reportable segment - the research, development, manufacture and distribution of hepatic delivery systems for the use in the treatment of specific conditions (the "reportable segment"). The Company's chief operating decision maker ("CODM") is comprised of a single management team consisting of the Chief Financial Officer, Chief Operating Officer, Chief Medical Officer and General Manager that reports to the Chief Executive Officer. The CODM uses consolidated gross profit and net income or loss, which can be found on the Consolidated Statements of Operations and Comprehensive Income (Loss), to assess financial performance. These financial metrics are used to monitor budget versus actual results. Significant segment expenses reviewed by the CODM are presented in the Company's Consolidated Statements of Operations and Comprehensive Income (Loss). The measure of segment assets provided to the chief operating decision maker is reported on the balance sheet as total consolidated assets.

DELCATH SYSTEMS, INC.
Notes to Consolidated Financial Statements
for the Years Ended December 31, 2025 and 2024
(amounts in thousands, except share and per share amounts)

Revenues from external customers are attributed to geographic areas based on the location of the customer. The following table shows the disaggregated revenue by geographic location for the twelve months ended December 31, 2025 and 2024. No individual foreign country is material to the consolidated results.

	Twelve Months Ended December 31,	
	2025	**2024**
Foreign	$ 6,396	$ 4,902
United States	78,835	32,303
Total revenue	$ 85,231	$ 37,205

As of December 31, 2025 and 2024, substantially all of the Company's long-lived assets were located in the United States; long-lived assets located in any individual foreign country were not material.

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 Financial 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 Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025.

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 Financial Officer, concluded that our internal control over financial reporting was effective as of December 31, 2025.

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 quarter ended December 31, 2025, no Director or Officer of the Company adopted, modified, or terminated a Rule 10b5-1 trading plan.

There were no "non-Rule 10b5-1 trading arrangements" as defined in Item 408 of Regulation S-K of the Exchange Act adopted, modified or terminated during the three months ended December 31, 2025 by our Section 16 officers or directors.

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 2026 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2025, 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 Annual Report on Form 10-K, and the inclusion of such website address in this Annual Report on Form 10-K 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.

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K. In addition, it is the Company's practice to comply with the applicable laws and regulations relating to insider trading.

Item 11. Executive Compensation

The information required by this Item will be set forth in our proxy statement for the 2026 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2025, 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 2026 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2025, 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 2026 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2025, 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 2026 Annual Meeting of Stockholders of the Company, to be filed with the SEC within 120 days of December 31, 2025, 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, 2025 and 2024;
    - Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2025 and 2024;
    - Consolidated Statements of Stockholders' Equity for the years ended December 31, 2025 and 2024;
    - Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024; 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 3.1 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2025).
4.1	Description of Securities (incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 10-K filed with the Commission on March 6, 2025).
4.2	Form of Amendment of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 30, 2024).
10.1#	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 May 16, 2025).
10.2#	Form of Stock Option Agreement under the 2020 Omnibus Equity Incentive Plan, as amended
10.3#	Forms of Restricted Stock Unit Agreement and Notice of Grant of Restricted Stock Unit under the 2020 Omnibus Equity Incentive Plan, as amended
10.4#	Executive Employment Agreement dated July 16, 2024, 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 July 19, 2024).
10.5#	Executive Employment Agreement dated July 17, 2024, by and between Delcath Systems, Inc. and Sandra Pennell (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 19, 2024).
10.6#	Executive Employment Agreement dated July 17, 2024, by and between Delcath Systems, Inc. and Kevin Muir (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 19, 2024).
10.7#	Delcath Systems, Inc. 2023 Inducement Plan, as amended (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 6, 2025).
10.8#	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).

Exhibit No.	Description
10.9#	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).
10.10#	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).
10.11#	Delcath Systems, Inc. 2021 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.2 on Form 8-K filed on May 16, 2025).
10.12	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).
10.13	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).
10.14	Amendment to the License, Supply and Contract Manufacturing Agreement, entered into on April 22, 2024 and effective as of May 1, 2024, by and between the Company and Synerx Pharma, LLC and Mylan Teoranta (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 5, 2024).
19.1**	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the Commission on March 6, 2025).
21**	Subsidiaries of the Company.
23.1**	Consent of Independent Registered Public Accounting Firm.
23.2**	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 (incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K filed March 26, 2024).
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

Exhibit No.	Description
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101

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

SIGNATURES

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

DELCATH SYSTEMS, INC.

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer
(Principal Executive Officer)
Dated: February 26, 2026

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)	February 26, 2026
/s/ Sandra Pennell Sandra Pennell	Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2026
/s/ John R. Sylvester John R. Sylvester	Chairman of the Board	February 26, 2026
/s/ Elizabeth Czerepak Elizabeth Czerepak	Director	February 26, 2026
/s/ Steven Salamon Steven Salamon	Director	February 26, 2026
/s/ Bridget Martell, MA, MD Bridget Martell, MA, MD	Director	February 26, 2026
/s/ Gil Aharon Gil Aharon	Director	February 26, 2026

DELCATH SYSTEMS, INC.

2020 OMNIBUS EQUITY INCENTIVE PLAN STOCK OPTION

AWARD AGREEMENT

(Incentive Stock Option)

THIS STOCK OPTION AWARD AGREEMENT (this "**Agreement**") is made as of Date of Award (the "**Grant Date**"), by and between Delcath Systems, Inc., a Delaware corporation (the "**Company**"), and the Recipient (the "**Optionee**") pursuant to the terms of the Company's 2020 Omnibus Equity Incentive Plan (the "**Plan**"). Capitalized terms used in this Agreement and not defined herein shall have the meanings ascribed to such terms in the Plan.

The parties hereto agree as follows:

1. Subject to Plan. The Optionee acknowledges and agrees that this Agreement has been executed and delivered pursuant to the terms and conditions of the Plan. The Optionee agrees to be bound by, and comply with, the terms of the Plan. All of the terms and conditions of the Plan which are not set forth in this Agreement are incorporated herein by reference. In the event that any provision of this Agreement conflicts with any term in the Plan, the term in the Plan shall be deemed controlling, unless the Plan specifically and expressly allows for modification of such term in the applicable Award Agreement, in which case this Agreement shall control.

2. Grant of Option. The Company grants to the Optionee an option (the "**Option**") to purchase [number of options granted] shares of Common Stock ("**Option Shares**") and, in connection with the Option, the Optionee shall be a Participant in the Plan. The Option is intended to qualify as an Incentive Stock Option under Section 422 of the Code (subject to the application of the
$100,000 limitation set forth in Section 422(d) of the Code). To the extent that the Option exceeds such $100,000 limitation, it shall be treated as a Non-Qualified Option.

3. Exercise Price. The Exercise Price to be paid by the Optionee to the Company upon the exercise of the Option shall be [$ grant exercise price] per Option Share, which is not less than the Fair Market Value of a share of Common Stock on the Grant Date.

4. Vesting Provisions.

(a) General. Provided that the Optionee remains in Service as of the applicable vesting date, the Option shall become vested and exercisable in equal monthly installments over the 36-month period beginning on the Grant Date (1/36th will vest on the first day of each month during said 36-month period, with the first vesting date being [grant date], provided that the Optionee remains in Service as of each such vesting date).

(b) Acceleration upon Change in Control. Provided that the Optionee remains in Service as of the consummation date of a Change in Control, any unvested portion of the Option that has not previously been forfeited or otherwise terminated will become vested and exercisable in full upon such consummation date.

5. Option Term

(a) Maximum Term. The Option, to the extent vested pursuant to Section 4 hereof (or otherwise hereunder or pursuant to terms of the Plan), may be exercised at any time on or after the applicable vesting date and prior to the termination of the Option. The Option shall expire and terminate on the tenth anniversary of the Grant Date, unless it is earlier terminated in accordance with the terms of the Plan or this Agreement (including without limitation, Section 5(b) hereof). Upon any such termination of the Option, the Option shall be forfeited and shall no longer be exercisable.

(b) Effect of Termination of Service.

i. Termination by Reason of Disability. In the event of the Optionee's termination of Service by reason of Disability, the Option, to extent vested and exercisable at the time of such termination of Service, shall terminate and no longer be exercisable upon the earlier of (A) the expiration date of the Option set forth in Section 5(a) hereof, and (B) the date that is 12 months following such termination of Service.

ii. Termination by Reason of Death. In the event of the Optionee's termination of Service by reason of death, the Option, to extent vested and exercisable at the time of such termination of Service, shall terminate and no longer be exercisable upon the earlier of (A) the expiration date of the Option set forth in Section 5(a) hereof, and
(B) the date that is 12 months following such termination of Service.

iii. Termination other than by Company for Cause. Except as provided in Section 5(b)(i) or (ii) (with respect to death or Disability), in the event of the Optionee's termination of Service for any reason (whether by the Company or the Optionee) other than by the Company or an Affiliate for Cause, the Option, to the extent vested and exercisable at the time of such termination of Service, shall terminate and no longer be exercisable upon the earlier of (A) the expiration date of the Option set forth in Section 5(a) hereof and (B) the 90th day following such termination of Service.

iv. Termination for Cause. In the event of the Optionee's termination of Service by the Company or an Affiliate for Cause, the Option (both the vested and unvested portion) shall terminate and no longer be exercisable upon the date of such termination of Service. If the Optionee's Service is suspended pending an investigation of whether the Optionee's Service will be terminated for Cause, all of the Optionee's rights under the Option, including the right to exercise the Option, shall be suspended during the investigation period.

v. Unvested Option. The Option, to the extent unvested as of the date of the Optionee's termination of Service for any reason, shall terminate upon the date of such termination of Service.

(c) No Notice of Option Expiration. The Optionee is responsible for keeping track of the expiration date of the Option and the post-termination exercise periods following the Optionee's termination of Service for any reason. The Company is not obligated to provide further notice of such periods.

6. Incentive Stock Option Qualification. The Optionee acknowledges that in order for the Option to qualify as an Incentive Stock Option, the Optionee must remain employed by the Company (or a Subsidiary) at least until three months before the Option is exercised (or, for purposes of this Agreement, 12 months in the case the Optionee terminates Service by reason of Disability, or 12 months in the case Optionee terminates Service by reason of death). If the Optionee sells or otherwise disposes of any of the Option Shares acquired pursuant to the Option on or before the later of (a) the date two years after the Grant Date, and (b) the date one year after issuance of such shares to the Optionee upon exercise of the Option, then such portion of the Option with respect to which such Option Shares are so disposed will not be deemed to be an Incentive Stock Option. The Optionee shall immediately notify the Company in writing of any such disposition. The Optionee agrees that he or she may be subject to income tax withholding by the Company on the compensation income recognized by the Optionee from the early disposition by payment in cash or out of the current wages or other compensation payable to the Optionee. Notwithstanding anything herein to the contrary, the Option shall not be transferable by the Optionee other than by will or by the laws of descent or distribution.

7. Procedure for Exercise.

(a) Notice of Exercise. The Option, to the extent vested and outstanding, may be exercised by delivering written notice of exercise to the Company, in the form required by the Committee. The notice must state the number of Option Shares to be purchased and must be accompanied by payment in full of the Exercise Price.

(b) Payment of Exercise Price. The Exercise Price may be paid by cash or a certified or bank cashier's check or wire transfer. The Committee may also allow any other method of payment permitted by Section 6(f) of the Plan in its discretion at the time of exercise, subject to any restrictions deemed necessary or appropriate by the Committee to facilitate compliance with Applicable Law. The Option may be exercised to purchase less than the total number of Option Shares subject to the Option.

(c) Delivery of Stock Certificates Upon Exercise. Subject to Section 9 hereof, upon the exercise of the Option, the Company shall mail or deliver to the Optionee (or beneficiary in the case of exercise by a beneficiary), as promptly as practicable, a stock certificate or certificates representing the Option Shares then purchased (or take such other action its deems advisable to evidence the issuance of the Option Shares then purchased).

Restrictions on Transfer. The Optionee acknowledges and agrees that the Option, and any right or interest therein, may not be sold, transferred, gifted, donated, pledged, hypothecated, disposed of or assigned by the Optionee, and may be exercised during the lifetime of the Optionee only by the Optionee (or during the period the Optionee is under a legal disability, by the Optionee's guardian or legal representative). However, in the event of the death of the Optionee, the Option may be transferred by will or the laws of descent or distribution.

8. Registration, Listing and Qualification of Shares. Upon the exercise of the Option at a time when there is not in effect a registration statement under the Securities Act relating to the Option Shares, by virtue of such exercise, the Optionee shall be deemed to represent and warrant to the Company that the Option Shares shall be acquired for investment and not with a view to the distribution thereof, and not with any present intention of distributing the same. The Optionee shall provide the Company with such additional or other representations and warranties as the Company may require in order to ensure compliance with applicable Federal and state securities, blue sky and all other Applicable Laws. No Option Shares shall be issued unless and until the Company and/or the Optionee shall have complied with all applicable Federal or state registration, listing and/or qualification requirements and all other requirements of Applicable Law.

9. Certain Plan Provisions. Without limiting any other provision of this Agreement or the Plan, the Optionee acknowledges that the Option shall be subject to Plan Sections 4(d) (Adjustments for Change in Common Stock, Etc.), Section 12 (Forfeiture Events) and Section 13 (Change in Control).

10. Optionee's Representations. The Optionee hereby represents and warrants to the Company that (i) the execution, delivery and performance of this Agreement by the Optionee does not and will not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which the Optionee is a party or by which the Optionee is bound and (ii) upon the execution and delivery of this Agreement by the Company, this Agreement shall be the valid and binding obligation of the Optionee, enforceable against the Optionee in accordance with its terms. The Optionee hereby acknowledges and represents that the Optionee has consulted with (or has had an opportunity to consult with) independent legal counsel regarding the Optionee's rights and obligations under this Agreement and that the Optionee fully understands the terms and conditions contained herein and therein.

11. Rights of Optionee. Nothing in this Agreement shall interfere or limit in any way the right of the Company or any Affiliate to terminate the Optionee's Service at any time for any reason (with or without Cause). Nothing in this Agreement shall confer upon the Optionee any right to future equity-based or other incentive awards and nothing in this Agreement shall provide for any adjustment to the number of Option Shares issued or issuable pursuant to the exercise the Option upon the occurrence of subsequent events except as provided in the Plan.

No Rights as a Stockholder. The Optionee shall not have any of the rights of a stockholder with respect to the Option Shares until the Option Shares have been issued to the Optionee upon the due exercise of the Option. No adjustment will be made for dividends or distributions or other rights for which the record date is prior to the date such Option Shares are issued.

12. Withholding of Taxes. The Option (including the issuance of Option Shares pursuant to the exercise of the Option) shall be subject to applicable tax withholding. The Company shall be entitled, as it deems necessary or desirable, to withhold from any amounts due and payable by the Company or any Affiliate to the Optionee (or secure payment from the Optionee in lieu of withholding) the amount of any withholding or other tax due with respect to the exercise of the Option, and, subject to Applicable Law, the Company may defer the issuance of any Option Shares in connection with the exercise of the Option unless indemnified by the Optionee (including by way of payment to the Company of an amount required to be withheld as a condition of Option exercise), to the Company's satisfaction, with respect to liabilities relating to tax withholdings. In this regard, the Optionee authorizes the Company or any Affiliate, or their respective agents, at their discretion, to satisfy the obligations with regard to all applicable tax withholdings by one or a combination of the following:

(a) withholding from the Optionee's wages or other cash compensation paid to the Optionee by the Company and/or any Affiliate;

(b) withholding from proceeds of the sale of Option Shares acquired at exercise of this Option either through a voluntary sale or through a mandatory sale arranged by the Company (on the Optionee's behalf pursuant to this authorization and without further consent);

(c) withholding Option Shares to be issued upon exercise of the Option, provided the Company only withholds a number of Option Shares necessary to satisfy no more than the withholding amounts determined based on the maximum permitted statutory rate applicable in the Optionee's jurisdiction;

(d) the Optionee's payment of a cash amount (including by check representing readily available funds or a wire transfer); or

(e) any other arrangement approved by the Committee and permitted under Applicable Law.

Personal Data. For the purpose of implementing, administering and managing the Plan, this Agreement and Option granted hereunder, the Optionee, by execution hereof, consents to the collection, receipt, use, retention and transfer, in electronic or other form, of the Optionee's personal data by and among the Company and its third party vendors or any potential party to any Change in Control transaction or capital raising transaction involving the Company. The Optionee understands that personal data (including but not limited to, name, home address, telephone number, employee number, employment status, social security number, tax identification number, date of birth, nationality, job and payroll location, data for tax withholding purposes and shares awarded, cancelled, exercised, vested and unvested) may be transferred to third parties assisting in the implementation, administration and management of this Agreement and Option and the Plan and the Optionee expressly authorizes such transfer as well as the retention, use, and the subsequent transfer of the data by the recipient(s). The Optionee understands that these recipients may be located in the Optionee's country or elsewhere, and that the recipient's country may have different data privacy laws and protections than the Optionee's country. The Optionee understands that data will be held only as long

as is necessary to implement, administer and manage this Option. The Optionee understands that he/she/it may, at any time, request a list with the names and addresses of any potential recipients of the personal data, view data, request additional information about the storage and processing of data, require any necessary amendments to data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing the Company's Secretary. The Optionee understands, however, that refusing or withdrawing the Optionee's consent may affect the Optionee's ability to accept or exercise this Option.

13. Consent to Electronic Delivery and Participation. By accepting this Option, the Optionee agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company, and consents to the electronic delivery of the Agreement, the Plan, account statements, prospectuses, and all other documents, communications, or information related to the Option. Electronic delivery may include the delivery of a link to the Company intranet or the internet site of a third party involved in administering the Agreement, the delivery of the document via e-mail, or such other delivery determined at the Company's discretion. The Optionee may receive from the Company a paper copy of any documents delivered electronically at no cost if the Optionee contacts the Company by telephone, through a postal service, or electronic mail to the appropriate Person designated by the Committee.

No Future Entitlement. By execution of this Agreement, the Optionee acknowledges and agrees that: (i) the grant of this Option is a one-time benefit which does not create any contractual or other right to receive future grants of stock options, or compensation in lieu of stock options, even if stock options have been granted repeatedly in the past; (ii) all determinations with respect to any such future grants, including, but not limited to, the times when stock options shall be granted or shall become exercisable, the maximum number of shares subject to each stock option, and the purchase price, will be at the sole discretion of the Committee; (iii) the value of this Option is not part of normal or expected compensation or salary for any purpose, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments or similar payments, or bonuses, long-service awards, pension or retirement benefits; (v) the vesting of this Option ceases upon termination of employment with the Company or transfer of employment from the Company, or other cessation of eligibility for any reason, except as may otherwise be explicitly provided in this Agreement or the Plan; (vi) if the underlying Common Stock does not increase in value, this Option will have no value, nor does the Company guarantee any future value; and (vii) no claim or entitlement to compensation or damages arises if the Common Stock does not increase in value, and the Optionee irrevocably releases the Company from any such claim that does arise.

14. General Provisions.

(a) Transfers in Violation of Agreement. Any transfer or attempted transfer of the Option in violation of any provision of this Agreement or the Plan shall be null and void and of no force and effect and the purported transferee shall have no rights or privileges in or with respect to the Option or the Option Shares.

(b) Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any Applicable Law in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or the enforceability of this Agreement in any other jurisdiction, but this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

(c) Complete Agreement. This Agreement, the Plan and any other documents expressly referred to herein and therein, embody the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements and representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way.

(d) Counterparts. This Agreement may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement.

(e) Successors and Assigns. Except as otherwise provided herein, this Agreement shall bind and inure to the benefit of, and be enforceable by, the Optionee and the Company and their respective successors and assigns; provided, that the rights and obligations of the Optionee under this Agreement shall not be assignable except as may otherwise be expressly permitted in this Agreement or in the Plan.

(f) Choice of Law. This Agreement shall be construed, interpreted and the rights of the parties determined in accordance with the laws of the State of Delaware (without reference to any choice of law rules that would require the application of the laws of any other jurisdiction). Each of the Company and the Optionee waives the necessity for personal service of any and all process upon such party and consents that all such service of process may be made by registered or certified mail (return receipt requested), in each case directed to such party at the address set forth in the Company's records, and service so made will be deemed to be completed on the date of actual receipt. Each of the Company and the Optionee consents to service of process as aforesaid. Nothing in this Agreement will prohibit personal service in lieu of the service by mail contemplated herein.

Amendment. The provisions of this Agreement may be amended by the Committee at any time; provided, however, that the Committee may not change any term of this Agreement in a manner

which would have a materially adverse effect on the Optionee without the Optionee's approval, unless such an amendment is required by Applicable Law or otherwise expressly permitted by the terms of the Plan. Notwithstanding the foregoing, to the extent that any amendment to the Plan affects the terms of this Agreement, the Optionee and any permitted assigns shall be deemed to have consented to such amendment.

(g) Interpretation. All questions of interpretation concerning this Agreement and/or the Plan shall be determined by the Committee. All determinations by the Committee shall be final and binding upon all persons having an interest in the Option as provided by the Plan. Any officer (other than the Optionee) shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, or election which is the responsibility of or which is allocated to the Company herein or in the Plan, provided that the officer has apparent authority with respect to such matter, right, obligation, or election.

(h) Further Instruments. The Committee may require that the Optionee execute any agreements (or the Committee may otherwise impose other requirements) with such terms as the Committee deems appropriate, with respect to the Option or the Option Shares. The Optionee shall execute any additional documents the Committee deems necessary or advisable in order to carry out or effect one or more of the obligations or restrictions imposed on the Optionee pursuant to the terms of the Plan and this Agreement.

(i) Section 409A. The Option is intended to be exempt from Section 409A of the Code, and the Plan and this Agreement shall be administered and interpreted consistent with such intent. Notwithstanding the foregoing, the Company makes no representations that the Option or the vesting and payments provided by this Agreement are exempt from or comply with Section 409A of the Code, and in no event shall the Company or any Affiliate be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Optionee on account of non-compliance with Section 409A of the Code.

[*Remainder of Page Intentionally Left Blank*]

DELCATH SYSTEMS, INC.

2020 OMNIBUS EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

THIS RESTRICTED STOCK UNIT AWARD AGREEMENT (together with the Notice of Restricted Stock Unit Award, this "**Agreement**") is made as of the Date of Award (the "**Grant Date**"), as defined under the Notice of Restricted Stock Unit Award ("**Grant Notice**"), by and between Delcath Systems, Inc., a Delaware corporation (the "**Company**"), and the Participant.

The parties hereto agree as follows:

1. Restricted Stock Unit Award.

(a) The Company, pursuant to its 2020 Omnibus Equity Incentive Plan (the "**Plan**"), hereby grants to the Participant a Restricted Stock Unit Award with respect to the number of Restricted Stock Units set forth in the Grant Notice. This Restricted Stock Unit Award is subject to all of the terms and conditions as set forth herein and in the Plan which is attached hereto **Attachment I** and is hereby incorporated by reference. Capitalized terms used in this Agreement and not defined herein shall have the meanings ascribed to such terms in the Plan. In the event that any provision of this Agreement conflicts with any term in the Plan, the term in the Plan shall be deemed controlling.

(b) This Restricted Stock Unit Award represents the right to be issued on a future date the number of shares of Common Stock that is equal to the number of Restricted Stock Units as indicated in the Grant Notice, as modified to reflect any capitalization adjustments and subject to the Participant's satisfaction of the vesting conditions set forth therein. Any additional Restricted Stock Units that become subject to the Restricted Stock Unit Award pursuant to capitalization adjustments as set forth in Section 4(d) of the Plan and the provisions of Section 4 below, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units covered by this Restricted Stock Unit Award.

(c) This Restricted Stock Unit Award is subject to all the provisions of the Plan, including but not limited to the provisions in Section 4(d) of the Plan (Adjustments for Change in Common Stock, Etc.), Section 12 of the Plan (Forfeiture Events), Section 13 of the Plan (Change in Control), Section 14(i) of the Plan (Tax Withholding), and Section 14(r) of the Plan (No Continued Service Rights).

2. Participation. The Participant shall be deemed a "Participant" for purposes of applying the terms of the Plan to this Agreement and the Restricted Stock Unit Award granted hereby.

3. Vesting Provisions.

(a) General. Provided that the Participant remains in Service as of each applicable vesting date, this Restricted Stock Unit Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, subject to the provisions contained herein and the terms of the Plan. The Restricted Stock Unit Award, to the

extent unvested as of the date of the Participant's termination of Service for any reason, shall terminate upon the date of such termination of Service.

(b) Acceleration upon Change in Control. Provided that the Participant remains in Service as of the consummation date of a Change in Control, any unvested portion of the Restricted Stock Unit Award that has not previously been forfeited or otherwise terminated will become vested in full upon such consummation date.

4. Withholding Obligations. Unless the Committee determines to require or permit the Participant to satisfy the U.S. federal, state, and local tax withholding obligations and non-U.S. tax withholding obligations, if any, which arise in connection with this Restricted Stock Unit Award (the "**Withholding Obligation**") in any other manner allowed by Section 14(i) of the Plan, the Company shall automatically withhold shares of Common Stock that are otherwise deliverable to the Participant in respect of the Restricted Stock Units in an amount necessary to satisfy any Withholding Obligation. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to the Participant any Common Stock in respect of the Restricted Stock Unit Award. In the event the Withholding Obligation of the Company arises prior to the delivery to the Participant of Common Stock or it is determined after the delivery of Common Stock to the Participant that the amount of the Withholding Obligation was greater than the amount withheld by the Company, the Participant agrees to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

5. Date of Issuance. The issuance of shares of Common Stock in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation, if any, in the event one or more Restricted Stock Units vests, the Company shall issue to the Participant one (1) share of Common Stock for each Restricted Stock Unit (subject to any adjustment under Section 4(d) of the Plan, and subject to any different provisions in the Grant Notice) that vests on the applicable vesting date(s) or on a later date as determined by the Company, but in no event later than (a) December 31 of the calendar year in which the applicable vesting date occurs (that is, the last day of the Participant's taxable year in which the applicable vesting date occurs), or (b) if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock issuable as a result of the applicable vesting date under the Restricted Stock Unit Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

6. Transferability. Except as otherwise provided in the Plan, this Restricted Stock Unit Award is not transferable, except by will or in accordance with the laws of descent and distribution.

7. No Rights as a Stockholder. The Participant shall not have any of the rights of a stockholder with respect to the shares of Common Stock underlying the Restricted Stock Unit Award unless and until such shares of Common Stock have been issued to the Participant in accordance with Section 6 hereof.

8. Change in Control. The Restricted Stock Unit Award is subject to the terms of any agreement governing a Change in Control involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

9. No Liability for Taxes. As a condition to accepting the Restricted Stock Unit Award, the Participant hereby (a) agrees to not make any claim against the Company, or any of its Officers,

Directors, Employees or Affiliates, related to tax liabilities arising from the Restricted Stock Unit Award or other Company compensation and (b) acknowledges that the Participant was advised to consult with the Participant's own personal tax, financial and other legal advisors regarding the tax consequences of the Restricted Stock Unit Award and has either done so or knowingly and voluntarily declined to do so.

10. Severability. If any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

11. Personal Data. For the purpose of implementing, administering and managing the Plan, this Agreement and the Restricted Stock Unit Award granted hereunder, the Participant, by execution hereof, consents to the collection, receipt, use, retention and transfer, in electronic or other form, of the Participant's personal data by and among the Company and its third party vendors or any potential party to any Change in Control transaction or capital raising transaction involving the Company. The Participant understands that personal data (including but not limited to, name, home address, telephone number, employee number, employment status, social security number, tax identification number, date of birth, nationality, job and payroll location, data for tax withholding purposes and shares awarded, cancelled, exercised, vested and unvested) may be transferred to third parties assisting in the implementation, administration and management of this Agreement, the Restricted Stock Unit Award and the Plan and the Participant expressly authorizes such transfer as well as the retention, use, and the subsequent transfer of the data by the recipient(s). The Participant understands that these recipients may be located in the Participant's country or elsewhere, and that the recipient's country may have different data privacy laws and protections than the Participant's country. The Participant understands that data will be held only as long as is necessary to implement, administer and manage this Restricted Stock Unit Award. The Participant understands that the Participant may, at any time, request a list with the names and addresses of any potential recipients of the personal data, view data, request additional information about the storage and processing of data, require any necessary amendments to data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing the Company's Secretary. The Participant understands, however, that refusing or withdrawing the Participant's consent may affect the Participant's ability to accept this Restricted Stock Unit Award or the shares of Common Stock underlying such award.

12. Consent to Electronic Delivery and Participation. By accepting this Restricted Stock Unit Award, the Participant agrees to participate hereunder through an on-line or electronic system established and maintained by the Company or a third party designated by the Company, and consents to the electronic delivery of the Agreement, the Plan, account statements, prospectuses, and all other documents, communications, or information related to the Restricted Stock Unit Award. Electronic delivery may include the delivery of a link to the Company intranet or the internet site of a third party involved in administering the Agreement, the delivery of the document via e-mail, or such other delivery determined at the Company's discretion. The Participant may receive from the Company a paper copy of any documents delivered electronically at no cost if the Participant contacts the Company by telephone, through a postal service, or electronic mail to the appropriate Person designated by the Committee.

13. No Future Entitlement. By execution of this Agreement, the Participant acknowledges and agrees that: (i) the grant of this Restricted Stock Unit Award is a one-time benefit which does not create any contractual or other right to receive future grants of equity or equity-based incentive awards, or compensation in lieu of equity or equity-based incentive awards, even if equity or equity-based incentive awards have been granted repeatedly in the past; (ii) all

determinations with respect to any such future grants, including, but not limited to, the times when any such equity or equity-based incentive awards shall be granted, the maximum number of shares subject to each such equity or equity-based incentive award, and any vesting conditions with respect thereto, will be at the sole discretion of the Committee; (iii) the value of this Restricted Stock Unit Award is not part of normal or expected compensation or salary for any purpose, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments or similar payments, or bonuses, long-service awards, pension or retirement benefits; and (iv) the vesting of this Restricted Stock Unit Award ceases upon termination of employment with the Company or transfer of employment from the Company, or other cessation of eligibility for any reason, except as may otherwise be explicitly provided in this Agreement or the Plan.

14. Other Documents. The Participant hereby acknowledges receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, the Participant acknowledges receipt of the Company's policy permitting certain individuals to sell Company shares only during certain "window" periods and/or otherwise restricting the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

15. General Provisions.

(a) Transfers in Violation of Agreement. Any transfer or attempted transfer of the Restricted Stock Unit Award in violation of any provision of this Agreement or the Plan shall be null and void and of no force and effect and the purported transferee shall have no rights or privileges in or with respect to the Restricted Stock Unit Award or the shares of Common Stock underlying such award.

(b) Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any Applicable Law in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or the enforceability of this Agreement in any other jurisdiction, but this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

(c) Complete Agreement. This Agreement (including the terms of the Plan as incorporated herein by reference) embodies the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements and representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way.

(d) Counterparts. This Agreement may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement.

(e) Successors and Assigns. Except as otherwise provided herein, this Agreement shall bind and inure to the benefit of, and be enforceable by, the Participant and the Company and their respective successors and assigns; provided, that the rights and obligations of the Participant under this Agreement shall not be assignable except as may otherwise be expressly permitted in this Agreement or in the Plan.

(f) Choice of Law. This Agreement shall be construed, interpreted and the rights of the parties determined in accordance with the laws of the State of Delaware

(without reference to any choice of law rules that would require the application of the laws of any other jurisdiction). Each of the Company and the Participant waives the necessity for personal service of any and all process upon such party and consents that all such service of process may be made by registered or certified mail (return receipt requested), in each case directed to such party at the address set forth in the Company's records, and service so made will be deemed to be completed on the date of actual receipt. Each of the Company and the Participant consents to service of process as aforesaid. Nothing in this Agreement will prohibit personal service in lieu of the service by mail contemplated herein.

(g) Amendment. The provisions of this Agreement may be amended by the Committee at any time; provided, however, that the Committee may not change any term of this Agreement in a manner which would have a materially adverse effect on the Participant without the Participant's approval, unless such an amendment is required by Applicable Law or otherwise expressly permitted by the terms of the Plan.

(h) Interpretation. All questions of interpretation concerning this Agreement shall be determined by the Committee. All determinations by the Committee shall be final and binding upon all persons having an interest in the Restricted Stock Unit Award as provided by the Plan. Any officer (other than the Participant) shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, or election which is the responsibility of or which is allocated to the Company herein or in the Plan, provided that the officer has apparent authority with respect to such matter, right, obligation, or election.

(i) Further Instruments. The Committee may require that the Participant execute any agreements (or the Committee may otherwise impose other requirements) with such terms as the Committee deems appropriate, with respect to the Restricted Stock Unit Award or the shares of Common Stock underlying such award. The Participant shall execute any additional documents the Committee deems necessary or advisable in order to carry out or effect one or more of the obligations or restrictions imposed on the Participant pursuant to the terms of this Agreement.

(j) Section 409A. The Restricted Stock Unit Award is intended to be exempt from, or in the alternative, to comply with, Section 409A of the Code, and this Agreement (including the Plan, as incorporated by reference herein) shall be administered and interpreted consistent with such intent. Notwithstanding the foregoing, the Company makes no representations that the Restricted Stock Unit Award or the vesting and payments provided by this Agreement are exempt from or comply with Section 409A of the Code, and in no event shall the Company or any Affiliate be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Participant on account of non-compliance with Section 409A of the Code.

(k) [*Remainder of Page Intentionally Left Blank*]

Notice of Restricted Stock Unit Award

Company Name Delcath Systems, Inc.

Plan 2020 Omnibus Equity Incentive Plan

Participant ID

Participant Name

Participant Address

Grant/Award Type Restricted Stock Unit

Number of Restricted Stock Units Granted

Date of Award

Vesting Schedule

Vesting Date	No. of Restricted Stock Units	Percent

SUBSIDIARIES OF THE REGISTRANT

1. Delcath Systems Limited, organized under the laws of Ireland.
2. Delcath UK Systems Limited, organized under the laws of England.
3. Delcath Systems GmbH, organized under the laws of Germany.
4. Delcath Systems B.V., organized under the laws of the Netherlands.
5. Delcath Systems S.R.L., organized under the laws of Italy.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 Nos. 333-289661, 333-251385, 333-262022, 333-265202, 333-276090, and 333-280550, and Form S-3 Nos. 333-260097, 333-267321, 333-269173, 333-272659, 333-278989, 333-280551, 333-235904, and 333-236100 of our report dated February 26, 2026 with respect to the consolidated financial statements of Delcath Systems Inc. as of December 31, 2025 and for the year then ended included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C

New York, NY
February 26, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 Nos. 333-289661, 333-251385, 333-262022, 333-265202, 333-276090, and 333-280550, and Form S-3 Nos. 333-260097, 333-267321, 333-269173, 333-272659, 333-278989, 333-280551, 333-235904, and 333-236100 of our report dated March 6, 2025, with respect to the consolidated financial statements of Delcath Systems Inc. as of December 31, 2024 and for the year then ended included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

New York, NY
February 26, 2026

Exhibit 31.1

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gerard Michel, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE
February 26, 2026

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sandra Pennell, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE
February 26, 2026

/s/ Sandra Pennell
Sandra Pennell
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerard Michel, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE
February 26, 2026

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer (Principal Executive Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Delcath Systems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

DELCATH SYSTEMS, INC.

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sandra Pennell, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE
February 26, 2026

/s/ Sandra Pennell
Sandra Pennell
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Delcath Systems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.