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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2025
Or

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.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

06-1245881
(I.R.S. Employer Identification No.)

566 Queensbury Avenue
Queensbury, NY 12804
(Address of principal executive offices)
(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

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 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 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
Non-accelerated filer

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 Securities Act.

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

As of May 6, 2025, 34,826,183 shares of the Company's common stock, \$0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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DEL CATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	\$ 12,776	\$ 32,412
Short-term investments	46,120	20,821
Accounts receivable	13,942	10,890
Inventories	7,132	6,933
Prepaid expenses and other current assets	4,379	2,704
Total current assets	84,349	73,760
Property, plant and equipment, net	1,954	1,790
Right-of-use assets	1,016	1,039
Total assets	\$ 87,319	\$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,619	\$ 961
Accrued expenses	3,558	5,078
Lease liabilities, current	110	105
Total current liabilities	5,287	6,144
Lease Liabilities, non-current	906	933
Other liabilities, non-current	896	766
Total liabilities	\$ 7,089	\$ 7,843
Commitments and contingencies (see Note 12)		
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; 14,192 and 14,192 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	—	—
Common stock, \$0.01 par value; 80,000,000 shares authorized; 33,436,612 shares and 33,061,002 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	334	331
Additional paid-in capital	609,994	599,881
Accumulated deficit	(530,479)	(531,548)
Accumulated other comprehensive income	381	82
Total stockholders' equity	80,230	68,746
Total liabilities and stockholders' equity	\$ 87,319	\$ 76,589

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Three months ended March 31,	
	2025	2024
Product revenue	\$ 19,784	\$ 3,139
Cost of goods sold	(2,845)	(903)
Gross profit	16,939	2,236
Operating expenses:		
Research and development expenses	5,007	3,700
Selling, general and administrative expenses	11,290	8,814
Total operating expenses	16,297	12,514
Operating gain (loss)	642	(10,278)
Change in fair value of warrant liability	—	(612)
Interest income (expense), net	618	(199)
Other income (expense)	4	(22)
Income (loss) before income taxes	1,264	(11,111)
Income tax expense	195	—
Net income (loss)	1,069	(11,111)
Other comprehensive income (loss):		
Unrealized gain on investments adjustments	239	8
Foreign currency translation adjustments	60	14
Total comprehensive income (loss)	\$ 1,368	\$ (11,089)
Common share data:		
Basic income (loss) per common share	\$ 0.03	\$ (0.45)
Weighted average number of basic shares outstanding	34,642,641	24,887,180
Diluted income (loss) per common share	\$ 0.03	\$ (0.45)
Weighted average number of dilutive shares outstanding	39,511,120	24,887,180

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DEL CATH SYSTEMS, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share data)

	Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	No. of Shares	Amount	No. of Shares	Amount				
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	—	—	—	—	6,813	—	—	6,813
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	50	—	—	50
Issuance of common stock with the Employee Stock Purchase Plan	—	—	35,513	—	238	—	—	238
Warrant Exercise - Series F	—	—	238,500	2	2,383	—	—	2,385
Stock Option Exercise	—	—	101,597	1	629	—	—	630
Net income	—	—	—	—	—	1,069	—	1,069
Unrealized gain on investment adjustments	—	—	—	—	—	—	239	239
Foreign currency translation adjustments	—	—	—	—	—	—	60	60
Balance at March 31, 2025	14,192	\$ —	33,436,612	\$ 334	\$ 609,994	\$ (530,479)	\$ 381	\$ 80,230

	Preferred Stock \$0.01 Par Value		Common Stock \$0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	No. of Shares	Amount	No. of Shares	Amount				
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	—	—	—	—	2,895	—	—	2,895
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	50	—	—	50
Private placement -issuance of common shares, net of expenses	—	—	876,627	8	6,904	—	—	6,912
Issuance of common stock with the Employee Stock Purchase Plan	—	—	21,140	—	74	—	—	74
Conversion - F-3 Preferred to Common	(8,010)	—	1,779,998	18	(17)	—	—	1
Net loss	—	\$ —	—	\$ —	—	\$ (11,111)	\$ —	\$ (11,111)
Unrealized gain on investments	—	—	—	—	—	—	8	8
Foreign currency translation adjustments	—	—	—	—	—	—	14	14
Balance at March 31, 2024	16,809	—	25,439,319	254	530,482	(516,273)	157	14,620

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DEL CATH SYSTEMS, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

(1) General

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. (“Delcath” or the “Company”) as of and for the three months ended March 31, 2025 and 2024 should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (the “Annual Report”), which was filed with the Securities and Exchange Commission (the “SEC”) on March 6, 2025 and may also be found on the Company’s website (www.delcath.com). In these notes to the interim condensed consolidated financial statements the terms “us”, “we” or “our” refer to Delcath and its consolidated subsidiaries.

Description of Business

The Company is an interventional oncology company focused on the treatment of primary and metastatic cancers 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 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.

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*. The current focus of the Company’s clinical development program is 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’s IND application 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. The study will take place at more than 20 sites across the United States and Europe, with patient enrollment expected to begin in the second half of 2025.

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 study will take place at more than 20 sites across the United States and Europe, with patient enrollment expected to begin in the fourth quarter of 2025.

The Company believes that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

Risks and Uncertainties

As detailed in the Company's 2024 Annual Report filed on Form 10-K, the Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the risks associated with developing product candidates and successfully launching and commercializing its drug/device combination products, the Company's ability to obtain regulatory approval of its such products in the United States and other geography markets, the uncertainty of the broad adoption of its approved products by physicians and consumers, and significant competition.

In addition, high rates of inflation have resulted in the United States Federal Reserve raising interest rates. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Furthermore, if additional banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company or its partners' ability to access existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on the Company's business and financial condition, including the Company's ability to access additional capital on favorable terms, or at all, which could in the future negatively affect the Company's ability to pursue its business strategy.

Furthermore, 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 March 31, 2025, the Company had cash and cash equivalents totaling \$12.8 million and short-term investments totaling \$46.1 million, as compared to cash and cash equivalents totaling \$32.4 million and short-term investments totaling \$20.8 million at December 31, 2024. During the three months ended March 31, 2025, cash provided by operating activities was \$2.2 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.

The Company's capital commitments over the next twelve months include \$5.3 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement. Additional capital commitments beyond the next twelve months include (a) \$1.2 million of lease liabilities; and (b) \$0.9 million for settlement of litigation with medac. For more information on the medac settlement, see Note 12 - "Commitments and Contingencies - medac Matter".

Basis of Presentation

These interim condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America ("GAAP") and with the SEC's instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all wholly owned subsidiaries and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim condensed consolidated financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and cash flows for the interim periods ended March 31, 2025 and 2024; however, certain information and footnote disclosures normally included in our audited consolidated financial statements which were included in the Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

There have been no material changes to our significant accounting policies as set forth in Note 3 Summary of Significant Accounting Policies to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Recent Accounting Pronouncements

No new accounting standards were adopted during the three months ended March 31, 2025.

(2) 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.

HEPZATO

The Company ships and sells the HEPZATO KIT 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 KIT. 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 4 for further information regarding consignment inventory.

Hospitals and treating centers may also elect to purchase HEPZATO KITS 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 the HEPZATO KIT revenue based on contracted rates stated in an approved contract or purchase order upon delivery to the customer. There are no contractual rights of returns, refunds or similar obligations.

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.

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Revenue by product for the periods indicated were as follows:

(In thousands)	Three Months Ended March 31,	
	2025	2024
CHEMOSAT	\$ 1,761	\$ 1,131
HEPZATO KIT	18,023	2,008
Total revenue	\$ 19,784	\$ 3,139

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 March 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 and/or accounts receivable concentration is greater than 10% of total revenue or total accounts receivable in the periods disclosed below:

For the three months ended and as of March 31, 2025	% of Revenue	% of Accounts Receivable
Customer 1	15.0 %	21.3 %
Customer 2	13.1 %	8.1 %
Customer 3	10.3 %	6.7 %
Customer 4	9.4 %	10.8 %

For the three months ended and as of March 31, 2024	% of Revenue	% of Accounts Receivable
Customer 1	52.4 %	46.7 %
Customer 2	5.8 %	11.7 %
Customer 3	5.8 %	11.7 %

(3) Investments

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

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

(In thousands)	March 31, 2025		
	Gross Unrealized		Estimated Fair Value
	Amortized Cost	Gains	
U.S. government agency bonds	\$ 45,746	\$ 374	\$ 46,120
Short-term investments			\$ 46,120

As of March 31, 2025, there was less than \$0.4 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:

(in thousands)	December 31, 2024		
	Gross Unrealized		Estimated Fair Value
	Amortized Cost	Gains	
U.S. government agency bonds	\$ 20,686	\$ 135	\$ 20,821
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.

(4) Inventory

Inventory consists of the following:

(In thousands)	March 31, 2025	December 31, 2024
Raw materials	\$ 3,861	\$ 3,849
Work-in-process	2,273	2,260
Finished goods	998	824
Total inventory	<u>\$ 7,132</u>	<u>\$ 6,933</u>

The Company has consignment agreements with approved hospitals and treatment centers. As of March 31, 2025, there was approximately \$0.5 million in finished goods held at hospitals and treatment centers.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(In thousands)	March 31, 2025	December 31, 2024
Clinical trial expenses	\$ 1,207	\$ 222
Insurance premiums	277	161
Professional services	821	762
Interest receivable	379	125
Licenses	996	990
Software	160	164
Taxes	60	45
Prepayments on project initiatives	269	—
Other	210	235
Total prepaid expenses and other current assets	<u>\$ 4,379</u>	<u>\$ 2,704</u>

(6) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(In thousands)	March 31, 2025	December 31, 2024	Estimated Useful Life
Buildings and land	\$ 1,318	\$ 1,318	30 years - Buildings
Enterprise hardware and software	1,813	1,811	3 years
Leaseholds	1,619	1,585	Lesser of lease term or estimated useful life
Equipment	1,792	1,671	7 years
Furniture	250	232	5 years
Equipment in process	177	127	
Property, plant and equipment, gross	<u>6,969</u>	<u>6,744</u>	
Accumulated depreciation	(5,015)	(4,954)	
Property, plant and equipment, net	<u>\$ 1,954</u>	<u>\$ 1,790</u>	

Depreciation expense for the three months ended March 31, 2025 and 2024 was less than \$0.1 million for each period.

(7) Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	March 31, 2025	December 31, 2024
Clinical expenses	\$ 697	\$ 615
Compensation, excluding taxes	1,861	3,471
ESPP withholding	125	240
Professional fees	321	57
Inventory	9	44
medac	217	208
Other	328	443
Total accrued expenses	<u>\$ 3,558</u>	<u>\$ 5,078</u>

(8) 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-

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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 three months ended March 31, 2025 and 2024, the Company recognized less than \$0.1 million of operating lease expense and less than \$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 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 March 31, 2025:

(In thousands)	U.S.	Ireland	Total
Operating cash flows for operating leases	\$ (36)	\$ (11)	\$ (47)
Weighted average remaining lease term	8.8	1.3	
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, 2025	\$ 108	\$ 32	\$ 140
Year ended December 31, 2026	144	26	170
Year ended December 31, 2027	148	—	148
Year ended December 31, 2028	152	—	152
Year ended December 31, 2029	157	—	157
Thereafter	643	—	643
Total	1,352	58	1,410
Less present value discount	(391)	(3)	(394)
Operating lease liabilities included in the condensed consolidated balance sheets at March 31, 2025	\$ 961	\$ 55	\$ 1,016

(9) 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 March 31, 2025, the Company has designated the following preferred stock:

Designated Preferred Shares	March 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 March 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.

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

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 March 31, 2025, there have been 7,125,000 shares of common stock reserved under the 2020 Plan of which 285,036 remained available to be issued.

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

On December 5, 2023, the Company's 2023 Inducement Plan (the "2023 Plan") was adopted by the Company's Board of Directors. The 2023 Plan is administered by a Compensation Committee of two or more Independent Directors appointed by the Board of Directors and is intended to provide for the grant of non-qualified stock options, stock appreciation rights,

restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed appropriate to incentivize employment with the Company. Awards from the 2023 Plan can only be granted to individuals who have not previously worked for the Company or have not worked for the Company for a bona fide period of time. As of March 31, 2025, there have been 800,000 shares of common stock reserved under the 2023 Plan, of which 161,000 remain available to be granted.

Stock Options

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

The Company values stock options using the Black-Scholes option pricing model and used the following assumptions, on a weighted-average basis, during the reporting periods:

	Three Months Ended March 31,	
	2025	2024
Expected terms (years)	5.7	5.6
Expected volatility	90.0%	115.0%
Risk-free interest rate	4.35%	4.19%
Expected dividends	0.00%	0.00%

The following is a summary of stock option activity for the three months ended March 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	2,356,163	15.97	9.8	
Exercised	(101,597)	6.20		
Expired	—	—		
Cancelled/Forfeited	(53,432)	9.80		
Outstanding at March 31, 2025	7,968,061	\$ 9.81	8.0	\$ 31,861
Exercisable at March 31, 2025	3,873,579	\$ 8.37	6.6	\$ 18,258
Unvested at March 31, 2025	4,094,482	\$ 11.17	9.3	\$ 13,603

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2025 and 2024 was \$12.05 and \$3.92, respectively. The aggregate intrinsic value of stock options exercised was \$0.8 million for the three months ended March 31, 2025. Total cash received as a result of stock option exercises was \$0.6 million for the three months ended March 31, 2025. No options were exercised during the same period in 2024.

The following is a summary of share-based compensation expense in the statement of operations:

(In thousands)	Three Months Ended March 31,	
	2025	2024
Selling, general and administrative	\$ 4,529	\$ 2,042
Research and development	1,568	647
Cost of goods sold	766	256
Total	\$ 6,863	\$ 2,945

At March 31, 2025, there was \$25.8 million of aggregate unrecognized compensation expense related to employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 1.14 years.

Common Stock Warrants

The following is a summary of common stock warrant activity for the three months ended March 31, 2025:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2025	3,193,275	\$ 5.80
Warrants issued	—	—
Warrants exercised	(238,500)	10.00
Outstanding and exercisable at March 31, 2025	<u>2,954,775</u>	<u>\$ 5.46</u>

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

Range of Exercise Prices	Warrants Exercisable	
	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)
\$0.01 ⁽¹⁾	1,341,375	
\$10.00 ⁽²⁾	1,613,400	0.1
	<u>2,954,775</u>	

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

(2) As of May 5, 2025, the expiration date of the Series F warrants, additional warrants totaling 1,377,275 were exercised with subsequent cash receipts of \$13.8 million.

Employee Stock Purchase Plan

In August 2021, the Company's Board of Directors, with shareholder approval in May 2022, adopted the Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for a maximum of 260,295 shares of common stock to be purchased by participating employees of which 148,506 have been issued as of March 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.

(10) Net Income (Loss) per Share

Basic net income or loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities, except for those shares that are issuable for little or no cash consideration. Diluted net income or loss per share is determined by dividing net income or loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options, convertible preferred shares, and preferred and common warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

As of March 31, 2025 and 2024, the Company had 1,341,375 and 2,045,894 pre-funded warrants outstanding, respectively. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three months ended March 31, 2025 and 2024:

	Weighted average number of basic shares outstanding	
	Three months ended March 31,	
	2025	2024
Weighted average shares issued	33,301,266	23,705,374
Weighted average pre-funded warrants	1,341,375	1,181,806
Weighted average shares outstanding	<u>34,642,641</u>	<u>24,887,180</u>

Weighted average number of diluted shares outstanding

	Three months ended March 31,	
	2025	2024
Weighted average shares outstanding (Basic)	34,642,641	24,887,180
Additional dilutive shares	4,868,479	—
Weighted average shares outstanding (Diluted)	39,511,120	24,887,180

The following potentially dilutive securities were excluded from the computation of earnings per share as of March 31, 2025 and 2024 because their effects would be anti-dilutive:

	Three Months Ended March 31,	
	2025	2024
Common stock warrants	—	3,627,409
Assumed conversion of preferred stock warrants	—	4,149,994
Assumed conversion of preferred stock	—	2,564,911
Assumed conversion of convertible notes	—	488,031
Stock options	2,531,230	6,039,175
Assumed conversion of ESPP	22,057	16,586
Total	2,553,287	16,886,106

(11) Income Taxes

The Company has recorded a provision for income taxes of \$0.2 million for the quarter ended March 31, 2025. The Company had no provision for income taxes for the quarter ended March 31, 2024.

As discussed in “Note 16—Income Taxes” to the notes to the consolidated financial statements contained in the Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the United States, as well as various state and international jurisdictions. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations. Additional information regarding the statutes of limitations can be found in Note 16 - Income Taxes of the Company’s Annual Report.

The Inflation Reduction Act of 2022 included tax legislation that became effective in the first quarter of 2023. Significant legislation for corporate taxpayers includes a corporate alternative minimum tax of 15% for companies with \$1 billion or more in average net financial statement profits over the three previous years, as well as a 1% indirect excise tax on the repurchase of shares by a publicly traded company. The Company does not expect this legislation to have an effect on the tax provision as of March 31, 2025, however the Company will continue to evaluate the effect on the tax provision each reporting period.

(12) Commitments and Contingencies

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) 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. The Company has estimated the remaining fair value of the settlement to be \$1.1 million as of March 31, 2025 and recorded \$0.9 million as other liabilities, non-current and \$0.2 million as accrued expenses on the Company's condensed consolidated balance sheet as of March 31, 2025.

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 renew for successive 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 March 31, 2025, the Company has committed to purchase \$2.5 million of melphalan under this Supply Agreement in 2025.

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 treating sites as the studies progress. As of April 30, 2025, 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.

(13) Fair Value Measurements

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

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).

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The table below presents activity within Level 3 of the fair value hierarchy, our liabilities carried at fair value relating to the medac settlement, for the three months ended March 31, 2025:

(In thousands)	Level 3 Contingent liabilities
Balance at January 1, 2025	\$ 974
Liability fair value adjustment	99
Total change in foreign exchange	40
Balance at March 31, 2025	\$ 1,113

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

(In thousands)	March 31, 2025			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$ 11	\$ —	\$ —	\$ 11
U.S. government agency bonds	—	46,120	—	46,120
Total Assets	\$ 11	\$ 46,120	\$ —	\$ 46,131
Liabilities:				
Contingent Liability	\$ —	\$ —	\$ 1,113	\$ 1,113
Total Liabilities	\$ —	\$ —	\$ 1,113	\$ 1,113

(In thousands)	December 31, 2024			
	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

(14) 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 Loss, to assess financial performance. These financial metrics are used to monitor budget versus actual results. See Note 2 for a description of the

Company's disaggregated revenue by product line. Significant segment expenses reviewed by the CODM are presented in the Company's Consolidated Statements of Operations and Comprehensive Loss. The measure of segment assets provided to the chief operating decision maker is reported on the balance sheet as total consolidated assets.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the financial condition and results of operations of Delcath Systems, Inc. (“Delcath” or the “Company”) should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (the “Annual Report”), which was filed with the Securities and Exchange Commission (the “SEC”) on March 6, 2025, to provide an understanding of its results of operations, financial condition and cash flows.

All references in this Quarterly Report on Form 10-Q to “we,” “our,” “us” and the “Company” refer to Delcath Systems, Inc., and its subsidiaries unless the context indicates otherwise.

This Quarterly Report on Form 10-Q and may include trademarks, service marks and trade names owned or licensed by us, including CHEMOFUSE, CHEMOSAT, CHEMOSATURATION, DELCATH, HEPZATO, HEPZATO KIT, PHP and THE DELCATH PHP SYSTEM. Solely for convenience and readability, trademarks, service marks and trade names, including logos, artwork and other visual displays, may appear in a non-traditional trademark usage manner, including without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. All trademarks, service marks and trade names included in this Quarterly Report on Form 10-Q are the property of the Company or the Company’s licensor, as applicable.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 (the “Securities Act”). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in Item 3 “Quantitative and Qualitative Disclosures About Market Risk,” and the risks discussed in Part II, Item 1A under “Risk Factors” and the risks detailed from time to time in our future reports filed with the SEC. 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 Phase 2 clinical trial evaluating HEPZATO in combination with SOC for mCRC;
- our expectations that the publication of additional data from our Phase 3 FOCUS Trial, or any other trial that we initiate in the future, will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and support reimbursement in various jurisdictions, including the United States;
- our ability to successfully commercialize CHEMOSAT, HEPZATO KIT, and future products, if any, generate revenue and successfully obtain reimbursement for the products and/or the associated procedures;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of CHEMOSAT, HEPZATO 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;

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- 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 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 successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities; and
- contributions to adjusted EBITDA.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

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 KIT 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. As of April 30, 2025, 19 facilities have treated at least one patient with the HEPZATO KIT.

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 have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Our clinical development program for HEPZATO was comprised of the FOCUS Clinical Trial for Patients with metastatic hepatic dominant Uveal Melanoma (the “FOCUS Trial”), a global registration clinical trial that investigated objective response rate in patients with mUM. The current focus of our clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in patients with mUM, either as monotherapy or in combination with immunotherapy. On May 6, 2024, we announced the publication of results from our Phase 3 FOCUS Trial, including an Overall Response Rate (“ORR”) of 36.35, 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 standard of care (“SOC”) for liver-dominant metastatic colorectal cancer (“mCRC”) was cleared by the FDA in December 2024. The Phase 2 trial will evaluate the

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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. The study will take place at more than 20 sites across the United States and Europe, with patient enrollment expected to begin in the second half of 2025. The trial's primary endpoint, hepatic progression-free survival ("hPFS"), is anticipated to read out by the end of 2027, while overall survival ("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 liver-dominant metastatic breast cancer ("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 20 sites across the United States and Europe, with patient enrollment expected to begin in the fourth quarter of 2025. 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 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.

Results of Operations

(In thousands)	Three months ended March 31,	
	2025	2024
Total revenues	\$ 19,784	\$ 3,139
Cost of goods sold	(2,845)	(903)
Gross profit	16,939	2,236
Research and development expenses	5,007	3,700
Selling, general and administrative expenses	11,290	8,814
Total operating expenses	16,297	12,514
Operating gain (loss)	642	(10,278)
Interest and other income (expense)	622	(833)
Income tax expense	195	—
Net income (loss)	\$ 1,069	\$ (11,111)

Revenue

The increase in total revenue for the three months ended March 31, 2025 compared to the same periods in 2024 was due to the continued commercial expansion and demand of HEPZATO in the United States and CHEMOSAT in Europe. In the first quarter of 2024 there were 4 facilities that had treated at least one patient. As of March 31, 2025, 17 facilities were treating patients.

Cost of Goods Sold

The change in cost of goods sold for the three months ended March 31, 2025 compared to the same periods in 2024 is directly related to changes in demand for product revenue.

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 three months ended March 31, 2025 compared to the same period in 2024 is due to costs associated with expanding the clinical team and initiation of the Phase 2 clinical trial evaluating HEPZATO in combination with standard of care for mCRC. 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, rent and professional services such as accounting, legal, marketing and commercial preparation services. For the three months ended March 31, 2025 compared to the same periods in 2024, selling, general and administrative expenses increased due to continued commercial expansion activities including marketing-related expenses and additional personnel in the commercial team.

Interest and other Income/Expense

Interest and other income in 2025 is 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 three months ended March 31, 2025 due to all debt being paid off in 2024. There was no change in warrant valuation during the three months ended March 31, 2025 due to the exercise of all Tranche B Warrants in 2024.

Liquidity and Capital Resources

At March 31, 2025, we had cash and cash equivalents totaling \$12.8 million and short-term investments totaling \$46.1 million, as compared to cash, cash equivalents and restricted cash totaling \$32.4 million and short-term investments totaling \$20.8 million at December 31, 2024. During the three months ended March 31, 2025, \$2.2 million of cash was provided by operating activities compared to \$9.6 million used in operating activities during the three months ended March 31, 2024, no principal payments were made during the three months ended March 31, 2025, compared to \$3.1 million for principal payments during the three months ended March 31, 2024. At March 31, 2024, we had cash, cash equivalents and restricted cash totaling \$11.8 million.

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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 these consolidated financial statements. 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.

Capital Commitments

Our capital commitments over the next twelve months include (a) \$5.3 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement. Additional capital commitments beyond the next twelve months include (a) \$1.2 million of lease liabilities and (b) \$0.9 million for settlement of litigation with medac.

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. 238,500 Series F Warrants were exercised during the three months ended March 31, 2025 with an additional 1,377,275 Series F Warrants exercised after the quarter end and prior to their expiration.

Critical Accounting Estimates

There have been no material changes to the process of our critical accounting estimates as they were reported in our Annual Report on Form 10-K filed with the SEC on March 6, 2025.

Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. There were no material changes to our critical accounting policies as reported in our Annual Report. A description of certain accounting policies that may have a significant impact on amounts reported in the financial statements is disclosed in “Note 3 – Summary of Accounting Policies” to the notes to the consolidated financial statements contained in the Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer (its Certifying Officers), evaluated the effectiveness of the Company’s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of March 31, 2025, the Company’s Certifying Officers concluded that the Company’s disclosure controls and procedures were effective.

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The Company has established disclosure controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management of the Company, with the participation of its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. 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 12 - “*Commitment and Contingencies - medac Matter*” for more information.

Item 1A. Risk Factors

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described in the Annual Report on Form 10-K filed on March 6, 2025. Our business faces significant risks and uncertainties, and those described in our Annual Report may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the three months ended March 31, 2025, no Section 16 officers and directors adopted, modified or terminated a “Rule 10b5-1 trading arrangement” (as defined in Item 408 of Regulation S-K of the Exchange Act).

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 March 31, 2025 by our Section 16 officers or directors.

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Item 6. Exhibits

Exhibit No.	Description
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
3.4	<u>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).</u>
3.5	<u>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).</u>
3.6	<u>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 13, 2023).</u>
3.7	<u>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).</u>
3.8	<u>Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.8 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2024).</u>
31.1*	<u>Certification by Chief Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*</u>
31.2*	<u>Certification by Chief Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*</u>
32.1**	<u>Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**</u>
32.2**	<u>Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**</u>
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

+ This exhibit shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any filing, except to the extent the Company specifically incorporates it by reference.

DELCATH SYSTEMS, INC.

SIGNATURES

Pursuant to the requirements 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.

May 8, 2025

/s/ Gerard Michel

Gerard Michel
Chief Executive Officer
(Principal Executive Officer)

May 8, 2025

/s/ Sandra Pennell

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

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 Quarterly Report on Form 10-Q 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 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 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.

May 8, 2025

/s/ Gerard Michel

Gerard Michel
Chief Executive Officer
(Principal Executive Officer)

DEL CATH 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 Quarterly Report on Form 10-Q 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 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 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.

May 8, 2025

/s/ Sandra Pennell

Sandra Pennell

Chief Financial Officer

(Principal Financial and Accounting Officer)

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 Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended March 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.

May 8, 2025

/s/ Gerard Michel

Gerard Michel

Chief Executive Officer

(Principal Executive Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.

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 Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended March 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.

May 8, 2025

/s/ Sandra Pennell

Sandra Pennell

Chief Financial Officer

(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.