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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 September 30, 2026
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	**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)
(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	☐	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 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 October 30, 2026, 34,788,068 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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

	September 30, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 55,538	$ 43,454
Short-term investments	48,777	47,582
Accounts receivable	20,214	11,744
Inventories	10,501	10,252
Prepaid expenses and other current assets	6,525	6,498
Total current assets	141,555	119,530
Property, plant and equipment, net	5,127	3,166
Right-of-use assets	2,408	936
Total assets	$ 149,090	$ 123,632
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,475	$ 2,658
Accrued expenses	9,351	8,191
Lease liabilities, current	196	101
Total current liabilities	13,022	10,950
Lease liabilities, non-current	2,212	835
Other liabilities, non-current	319	628
Total liabilities	$ 15,553	$ 12,413
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 September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 34,771,239 shares and 34,691,671 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	348	347
Additional paid-in capital	653,118	639,145
Accumulated deficit	(520,298)	(528,848)
Accumulated other comprehensive income	369	575
Total stockholders' equity	133,537	111,219
Total liabilities and stockholders' equity	$ 149,090	$ 123,632

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Product revenue	$ 35,102	$ 20,563	$ 89,229	$ 64,503
Cost of goods sold	(3,918)	(2,624)	(10,639)	(8,787)
Gross profit	31,184	17,939	78,590	55,716
Operating expenses:				
Research and development expenses	11,011	7,986	31,215	19,875
Selling, general and administrative expenses	13,057	10,341	39,501	32,997
Total operating expenses	24,068	18,327	70,716	52,872
Operating income	7,116	(388)	7,874	2,844
Interest income	852	796	2,420	2,063
Other expense	(1)	(33)	(76)	(63)
Income before income taxes	7,967	375	10,218	4,844
Income tax expense (benefit)	1,015	(455)	1,668	248
Net income	6,952	830	8,550	4,596
Other comprehensive income (loss):				
Unrealized gain on investments adjustments	115	296	(135)	592
Foreign currency translation adjustments	(4)	(13)	(71)	201
Total comprehensive income	$ 7,063	$ 1,113	$ 8,344	$ 5,389
Common share data:				
Basic income per common share	$ 0.19	$ 0.02	$ 0.24	$ 0.13
Weighted average number of basic shares outstanding	36,074,348	36,383,277	35,996,019	35,610,619
Diluted income per common share	$ 0.17	$ 0.02	$ 0.21	$ 0.12
Weighted average number of dilutive shares outstanding	41,019,553	40,056,814	40,059,103	39,949,941

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DELCATH 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, 2026	14,192	$ —	34,691,671	$ 347	$ 639,145	$ (528,848)	$ 575	$ 111,219
Share-based compensation expense	—	—	—	—	4,876	—	—	4,876
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	70	—	—	70
Issuance of common stock with the Employee Stock Purchase Plan	—	—	46,008	—	389	—	—	389
Stock Option Exercise	—	—	43,431	—	230	—	—	230
Repurchase and retirement of common stock	—	—	(316,023)	(3)	(2,997)	—	—	(3,000)
Net loss	—	—	—	—	—	(1,070)	—	(1,070)
Unrealized gain on investment adjustments	—	—	—	—	—	—	45	45
Foreign currency translation adjustments	—	—	—	—	—	—	(49)	(49)
Balance at March 31, 2026	14,192	$ —	34,465,087	$ 344	$ 641,713	$ (529,918)	$ 571	$ 112,710
Share-based compensation expense	—	—	—	—	5,054	—	—	5,054
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	64	—	—	64
Stock Option Exercise	—	—	172,235	2	971	—	—	973
Repurchase and retirement of common stock	—	—	(1,070)	—	(11)	—	—	(11)
Net income	—	—	—	—	—	2,668	—	2,668
Unrealized gain on investment adjustments	—	—	—	—	—	—	(295)	(295)
Foreign currency translation adjustments	—	—	—	—	—	—	(18)	(18)
Balance at June 30, 2026	14,192	$ —	34,636,252	$ 346	$ 647,791	$ (527,250)	$ 258	$ 121,145
Share-based compensation expense	—	—	—	—	4,155	—	—	4,155
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	78	—	—	78
Issuance of common stock with the Employee Stock Purchase Plan	—	—	36,303	1	306	—	—	307
Stock Option Exercise	—	—	98,684	1	788	—	—	789
Net income	—	—	—	—	—	6,952	—	6,952
Unrealized gain on investment adjustments	—	—	—	—	—	—	115	115
Foreign currency translation adjustments	—	—	—	—	—	—	(4)	(4)
Balance at September 30, 2026	14,192	$ —	34,771,239	$ 348	$ 653,118	$ (520,298)	$ 369	$ 133,537

	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, 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
Compensation expense for issuance of stock options	—	—	—	—	7,159	—	—	7,159
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	50	—	—	50
Warrant Exercise - Series F	—	—	1,377,275	14	13,759	—	—	13,773
Stock Option Exercise	—	—	142,087	2	864	—	—	866
Net income	—	—	—	—	—	2,697	—	2,697
Unrealized gain on investment adjustments	—	—	—	—	—	—	57	57
Foreign currency translation adjustments	—	—	—	—	—	—	154	154
Balance at June 30, 2025	14,192	$ —	34,955,974	$ 350	$ 631,826	$ (527,782)	$ 592	$ 104,986
Compensation expense for issuance of stock options	—	—	—	—	5,567	—	—	5,567
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	81	—	—	81
Issuance of common stock with the Employee Stock Purchase Plan	—	—	22,858	—	243	—	—	243
Stock Option Exercise	—	—	330,107	3	2,854	—	—	2,857
Net income	—	—	—	—	—	830	—	830
Unrealized gain on investment adjustments	—	—	—	—	—	—	296	296
Foreign currency translation adjustments	—	—	—	—	—	—	$ (13)	$ (13)
Balance at September 30, 2025	14,192	$ —	35,308,939	$ 353	$ 640,571	$ (526,952)	$ 875	$ 114,847

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine months ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net income	$ 8,550	$ 4,596
Adjustments to reconcile net income to net cash provided by operating activities:		
Share-based compensation expense	14,297	19,720
Depreciation expense	368	158
Amortization of Right-of-Use Asset	132	82
Amortization of premiums and discounts on marketable securities	(1,328)	(1,238)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(27)	(3,919)
Accounts receivable	(8,470)	(2,861)
Inventories	(249)	(3,812)
Accounts payable and accrued expenses	1,977	1,800
Other liabilities, non-current	(505)	(258)
Net cash provided by operating activities	14,745	14,268
Cash flows from investing activities:		
Purchase of investments	(64,195)	(61,432)
Maturities of investments	64,193	36,400
Purchase of property, plant and equipment	(2,333)	(997)
Net cash used in investing activities	(2,335)	(26,029)
Cash flows from financing activities:		
Proceeds from the issuance of common stock relating to the employee stock purchase plan	696	481
Proceeds from exercise of warrants	—	16,158
Proceeds from exercise of stock options	1,992	4,353
Repurchase and retirement of common stock	(3,011)	—
Net cash (used in) provided by financing activities	(323)	20,992
Foreign currency effects on cash	(3)	170
Net increase in total cash	12,084	9,401
Total Cash and Cash Equivalents:		
Beginning of period	43,454	32,412
End of period	$ 55,538	$ 41,813

	For Nine months ended September 30,	
	2026	**2025**
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right of use assets obtained in exchange for lease obligations	$ 1,666	$ —

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DELCATH 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 and nine months ended September 30, 2026 and 2025 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, 2025 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on February 26, 2026 and may also be found on the Company's website (www.delcath.com). The information contained on, or that can be accessed through, our website is not incorporated by reference into these financial statements or in any report or document we have filed or may file with the SEC and any reference to our website address is intended to be an inactive textual reference only. 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 cancers primary to 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 U.S. 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 systemic administration of the 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 (adjusted HR 0.34; p=0.0002). 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 (adjusted HR = 0.39; p = 0.0065), median PFS 12.8 months versus 8.3 months (adjusted HR = 0.34; p=0.0002) 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 (82% versus 41%, P=0.0006), but most were self-limiting and 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. 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. On December 31, 2025, the Company announced the publication of subgroup analyses of the Phase 3 FOCUS Trial in the Journal of Cancer Research and Clinical Oncology. Currently, the Company's clinical development program is seeking to generate clinical data for CHEMOSAT and HEPZATO either as a monotherapy or in combination with immunotherapy. The Company expects that this will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe and support reimbursement in various jurisdictions, including the United States for HEPZATO.

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, metastatic pancreatic cancer, intrahepatic cholangiocarcinoma and non-small cell lung cancer. 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. Patient enrollment began in the third quarter of 2026.

Risks and Uncertainties

As detailed in the Annual Report, 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 for additional indications, obtaining regulatory approval of its products in the United States and other geographies for additional indications, the uncertainty of the broad adoption of its approved products by physicians and consumers, obtaining and maintaining sufficient reimbursement for approved products and/or the associated procedures to healthcare professionals and treating facilities, and significant competition.

Factors such as geopolitical events, including war, terrorism and civil and political unrest, such as the ongoing conflicts in the Middle East and between Russia and Ukraine, 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, shortages and delays in manufacturing the Company's products, which could have an adverse impact on its results of operations or cause an increase in the cost of ongoing or planned clinical trials. The Company 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 its manufacturing costs, cause it to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish its profitability or damage its reputation.

The United States has announced and implemented a broad range of tariffs on goods imported into the United States, many of which were then paused or cancelled. The majority of the Company's sales are domestic, though CHEMOSAT is sold only outside of the United States, 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 its overall manufacturing costs. The Company will continue to monitor the implementation and effect of existing and other proposed tariffs and other geopolitical events, such as the ongoing conflicts in the Middle East and between Russia and Ukraine and may take actions as a result thereof in order to attempt to alleviate certain risks and uncertainties that may be caused by such events.

Liquidity

The accompanying condensed 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.

At September 30, 2026, the Company had cash and cash equivalents totaling $55.5 million and short-term investments totaling $48.8 million. Net cash provided by operating activities for the nine months ended September 30, 2026 was $14.7 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.

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 September 30, 2026 and 2025; 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

Management has performed its quarterly evaluation of policies and 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 Annual Report.

Recent Accounting Pronouncements

No new accounting standards were adopted during the nine months ended September 30, 2026. The Company's management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statements presentation or disclosures.

ASU 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40)

In September 2025, the Financial Accounting Standards Board ("FASB") issued ASU 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. Such standard is intended to modernize old internal-use software guidance and expand the existing guidance on capitalizing implementation costs for cloud computing arrangements that are service contracts. The effective date for this standard is for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years. Early adoption is permitted as of the beginning of an annual reporting period. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

ASU 2024-03, Disaggregation of Income Statement Expenses

In November 2024, the 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.

(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 from Contracts with Customers: (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 September 30, 2026 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 4 - *Inventory*" 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. As of September 30, 2026, the Company had not identified any reported Medicaid utilization of its products within CMS' State Utilization that would give rise to a rebate obligation under the NDRA; accordingly, no rebate liability was accrued.

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 condensed consolidated balance sheets.

The NDRA, the PPA, and the agreement with the VA require 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2026	2025	2026	2025
CHEMOSAT	$ 2,426	$ 1,310	$ 6,145	$ 4,727
HEPZATO KIT	32,676	19,253	83,084	59,776
Total revenue	$ 35,102	$ 20,563	$ 89,229	$ 64,503

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 September 30, 2026, there were no estimated losses applied to the accounts receivable 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 the Company's total revenue or total accounts receivable in the periods disclosed below:

For the nine months ended and as of September 30, 2026	% of Revenue	% of Accounts Receivable
Customer 1	17.8 %	15.9 %
Customer 2	13.5 %	12.2 %
Customer 3	6.5 %	11.2 %

For the nine months ended and as of September 30, 2025	% of Revenue	% of Accounts Receivable
Customer 1	13.9 %	15.0 %
Customer 2	11.3 %	16.4 %
Customer 3	10.1 %	4.1 %
Customer 4	5.8 %	10.9 %

Customer concentrations may vary from period to period as demand for the Company's products fluctuates among customers. Accordingly, the customers identified as Customer 1, Customer 2, and Customer 3 in each period presented are not necessarily the same customers across periods.

(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 September 30, 2026:

	September 30, 2026		
(In thousands)	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
U.S. government agency bonds	$ 48,383	$ 394	$ 48,777
Total short-term investments			$ 48,777

As of September 30, 2026, 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, 2025:

	December 31, 2025		
(In thousands)	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
U.S. government agency bonds	$ 47,053	$ 529	$ 47,582
Total 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.

(4) Inventory

Inventory consists of the following:

(In thousands)	September 30, 2026	December 31, 2025
Raw materials	$ 5,982	$ 6,477
Work-in-process	3,492	2,809
Finished goods	1,027	966
Total inventory	$ 10,501	$ 10,252

The Company has consignment agreements with approved hospitals and treatment centers. As of September 30, 2026, there was approximately $0.8 million in finished goods held at hospitals and treatment centers.

During the nine months ended September 30, 2026, the Company has included a reserve of $0.5 million for inventory expected to expire prior to usage.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(In thousands)	September 30, 2026	December 31, 2025
Clinical trial expenses	$ 2,445	$ 2,405
Insurance premiums	209	547
Professional services	717	804
Interest receivable	499	499
Licenses	812	613
Software	1,329	706
Taxes	102	696
Other	412	228
Total prepaid expenses and other current assets	$ 6,525	$ 6,498

(6) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(In thousands)	September 30, 2026	December 31, 2025	Estimated Useful Life
Land, buildings and land improvements	$ 1,640	$ 1,557	30 years - Buildings 15 years - Land Improvements
Enterprise hardware and software	1,817	1,819	3 years
Leaseholds	1,654	1,648	Lesser of lease term or estimated useful life
Equipment	5,180	2,894	7 years
Furniture	258	251	5 years
Equipment in process	176	245	
Property, plant and equipment, gross	10,725	8,414	
Accumulated depreciation	(5,598)	(5,248)	
Property, plant and equipment, net	$ 5,127	$ 3,166	

Depreciation expense for the three and nine months ended September 30, 2026 was $0.2 million and $0.4 million, respectively. Depreciation for the three and nine months ended September 30, 2025 was less than $0.1 million and $0.2 million, respectively.

(7) Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	September 30, 2026	December 31, 2025
Clinical expenses	$ 1,885	$ 2,065
Compensation, excluding taxes	5,513	4,248
ESPP withholding	241	396
Professional fees	632	736
Inventory	—	74
medac	276	235
Other	804	437
Total accrued expenses	$ 9,351	$ 8,191

(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-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 the three and nine months ended September 30, 2026, the Company recognized approximately $0.1 million and $0.2 million of operating lease, respectively, and less than $0.1 million of short-term lease expense for both periods. For both the three and nine months ended September 30, 2025, the Company recognized approximately $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. The Company elected not to renew this lease and the lease expired upon its terms on August 2, 2026.

On September 30, 2026, the Company entered into a lease agreement (the "Warehouse Lease") to lease approximately 10,000 square feet of warehouse space in Queensbury, New York that will commence on December 1, 2026. The initial term of the lease is five years with a right to extend the lease by an additional five years. The Company's annual rent expense under the Warehouse Lease is $0.1 million for the first five-year term.

On May 25, 2026, the Company entered into a lease agreement (the "Galway Lease") to lease approximately 6,700 square feet of distribution and office space in Galway, Ireland. The term of the lease is ten years. The Company's annual rent expense under the Galway Lease is approximately $0.2 million for the first five years. A rent review will occur at the end of the fifth year with an increase or decrease in line with the cumulative movement in the Consumer Price Index with a total increase or decrease not to exceed 3%.

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 September 30, 2026:

(In thousands)	U.S.	Ireland	Total
Operating cash flows for operating leases	$ (108)	$ (118)	$ (226)
Weighted average remaining lease term	7.3	9.6	
Weighted average discount rate - operating leases	8 %	7 %	

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	$ 36	$ 55	$ 91
Year ended December 31, 2027	148	184	332
Year ended December 31, 2028	152	184	336
Year ended December 31, 2029	157	184	341
Year ended December 31, 2030	158	184	342
Thereafter	486	1,354	1,840
Total	1,137	2,145	3,282
Less present value discount	(282)	(592)	(874)
Operating lease liabilities included in the condensed consolidated balance sheets at September 30, 2026	$ 855	$ 1,553	$ 2,408

(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 September 30, 2026, the Company has designated the following preferred stock:

Designated Preferred Shares	September 30, 2026
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 September 30, 2026, 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 $25.0 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 September 30, 2026, there have been 945,665 shares of common stock repurchased and retired under the repurchase program at an average price paid per share of $9.5085 for a total aggregate purchase price of approximately $9.0 million, which includes 628,572 shares of common stock repurchased prior to 2026 for an aggregate purchase price of $6.0 million. The Company had approximately $16.0 million remaining under the share repurchase program at September 30, 2026.

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 share-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 September 30, 2026, there have been 11,125,000 shares of common stock reserved under the 2020 Plan, which includes the additional 1,800,000 shares approved by shareholders on May 13, 2026, of which 2,609,402 shares of common stock remained available to be issued as of September 30, 2026 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 share-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 September 30, 2026, there have been 1,100,000 shares of common stock reserved under the 2023 Plan, of which 56,122 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:

	Nine Months Ended September 30,	
	2026	**2025**
Expected terms (years)	5.7	5.7
Expected volatility	70.5%	89.1%
Risk-free interest rate	3.77%	4.30%
Expected dividends	0.00%	0.00%

The following is a summary of stock option activity for the nine months ended September 30, 2026:

	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, 2026	7,785,149	$ 10.05	7.8	$ 17,391
Granted	1,034,869	9.64	9.2	
Exercised	(314,350)	6.33		
Expired	(66,788)	13.54		
Cancelled/Forfeited	(125,114)	11.49		
Outstanding at September 30, 2026	8,313,766	$ 10.09	7.2	$ 49,859
Exercisable at September 30, 2026	6,148,119	$ 9.35	6.8	$ 41,477
Unvested at September 30, 2026	2,165,647	$ 12.21	8.6	$ 8,382

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and 2025 was $6.17 and $11.71, respectively. The aggregate intrinsic value of stock options exercised was $1.9 million and $3.0 million for the nine months ended September 30, 2026 and September 30, 2025, respectively. Total cash received as a result of stock option exercises was $2.0 million and $4.4 million for the nine months ended September 30, 2026 and September 30, 2025, respectively.

Restricted Stock Units

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

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2026	—	$ —
Granted	989,977	9.74
Vested	—	—
Forfeited	(53,517)	9.35
Outstanding at September 30, 2026	936,460	$ 9.76

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2026	2025	2026	2025
Selling, general and administrative	$ 2,702	$ 3,566	$ 9,385	$ 12,813
Research and development	1,184	1,551	3,862	4,892
Cost of goods sold	347	531	1,050	2,015
Total	$ 4,233	$ 5,648	$ 14,297	$ 19,720

At September 30, 2026, there was $12.4 million of aggregate unrecognized compensation expense related to employee and board stock option grants and restricted stock unit grants. The cost is expected to be recognized over a weighted average period of 0.97 years.

Common Stock Warrants

The following is a summary of common stock warrant activity for the nine months ended September 30, 2026:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2026	1,341,375	$ 0.01
Warrants issued	—	—
Warrants exercised	—	—
Warrants canceled	—	—
Outstanding and exercisable at September 30, 2026	1,341,375	$ 0.01

The following table presents information related to common stock warrants outstanding at September 30, 2026:

	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.

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, of which 253,675 have been issued as of September 30, 2026 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 income or 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, restricted stock units and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options, restricted stock units, 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.

At both September 30, 2026 and 2025, the Company had 1,341,375 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three and nine months ended September 30, 2026 and 2025:

Weighted average number of basic shares outstanding

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Weighted average shares issued	34,732,973	35,041,902	34,654,644	34,269,244
Weighted average pre-funded warrants	1,341,375	1,341,375	1,341,375	1,341,375
Weighted average shares outstanding	36,074,348	36,383,277	35,996,019	35,610,619

Weighted average number of diluted shares outstanding

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Weighted average shares outstanding (Basic)	36,074,348	36,383,277	35,996,019	35,610,619
Additional dilutive shares	4,945,205	3,673,537	4,063,084	4,339,322
Weighted average shares outstanding (Diluted)	41,019,553	40,056,814	40,059,103	39,949,941

The following potentially dilutive securities were excluded from the computation of earnings per share as of September 30, 2026 and 2025 because their effects would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options and Restricted Stock Units	2,529,244	3,510,565	2,529,244	3,510,565
Assumed conversion of ESPP	35,911	42,570	35,911	42,570
Total	2,565,155	3,553,135	2,565,155	3,553,135

(11) Income Taxes

The Company has recorded a provision for income taxes of $1.7 million and $0.2 million for the nine months ended September 30, 2026 and September 30, 2025, respectively.

As discussed in “Note 14 - 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 U.S., 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 14 Income Taxes of the Annual Report.

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, including full expensing of U.S. research and development costs under Section 174A, and retroactive expensing of unamortized U.S. research and development costs capitalized between 2022 and 2024. Additional information regarding the effect of OBBBA on the Company’s tax provision can be found in Note 14 Income Taxes of the Annual Report.

(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 $0.6 million as of September 30, 2026 and recorded $0.3 million as other liabilities, non-current and $0.3 million as accrued expenses on the Company's condensed consolidated balance sheet as of September 30, 2026.

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 September 30, 2026, the Company has committed to purchase $2.5 million of melphalan under this Supply Agreement in 2027.

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 $2.4 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

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, our liabilities carried at fair value relating to the medac settlement, for the nine months ended September 30, 2026:

	Level 3
(In thousands)	**Contingent liabilities**
Balance at January 1, 2026	$ 864
Change due to liability payment	(235)
Liability fair value adjustment	(12)
Total change in foreign exchange	(22)
Balance at September 30, 2026	$ 595

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: 4.00%
- Timing of expected payments: 1 - 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 September 30, 2026 and December 31, 2025 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value.

	September 30, 2026			
(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	—	48,777	—	48,777
Total Assets	$ 2	$ 48,777	$ —	$ 48,779
Liabilities:				
Contingent Liability	$ —	$ —	$ 595	$ 595
Total Liabilities	$ —	$ —	$ 595	$ 595

	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	$ 47,582	$ —	$ 47,584
Liabilities:				
Contingent Liability	$ —	$ —	$ 864	$ 864
Total Liabilities	$ —	$ —	$ 864	$ 864

(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 and includes the Chief Executive Officer. The CODM uses consolidated gross profit and net income or loss, which can be found on the Condensed Consolidated Statements of Operations and Comprehensive Income, 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 Condensed Consolidated Statements of Operations and Comprehensive Income. The measure of segment assets provided to the CODM is reported on the balance sheet as total consolidated assets.

Revenues from external customers are attributed to geographies based on the location of the customer. The following table shows the disaggregated revenue by geography for the three and nine months ended September 30, 2026 and 2025. No individual foreign country is material to the consolidated results.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Foreign	$ 2,426	$ 1,310	$ 6,145	$ 4,727
United States	32,676	19,253	83,084	59,776
Total revenue	$ 35,102	$ 20,563	$ 89,229	$ 64,503

As of September 30, 2026 and 2025, 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.

(15) Subsequent Events

The Company has evaluated subsequent events for adjustment to or disclosure in these condensed consolidated financial statements through the date of this report and has not identified any recordable or disclosable events not otherwise reported in these financial statements or the notes thereto.

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, 2025 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on February 26, 2026, 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 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 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, the HEPZATO KIT, and future products, if any, generate additional revenue and successfully obtain and maintain reimbursement to healthcare professionals and treating facilities for the products and/or the associated procedures;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of CHEMOSAT, the HEPZATO KIT, and future products, if any;
- the rate and degree of market acceptance and clinical utility of CHEMOSAT, the 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, the 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 the HEPZATO KIT;
- our ability to successfully manufacture CHEMOSAT and the 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. 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 to 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.

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 14 - "*Segment Information*" in the accompanying notes to our condensed consolidated financial statements for further detail.

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 a 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. Patient enrollment began in the third quarter of 2026. The trial's primary endpoint, hPFS, is anticipated to read out by the end of 2028, while OS results, a secondary endpoint, are 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 share-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, we 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 systemic administration of the 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 (adjusted HR 0.34; p=0.0002). 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 (adjusted HR = 0.39; p = 0.0065), median PFS 12.8 months versus 8.3 months (adjusted HR = 0.34; p=0.0002) 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 (82% versus 41%, P=0.0006), but most were self-limiting and 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.

Results of Operations

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	**2026**	**2025**	**2026**	**2025**
Total revenues	$ 35,102	$ 20,563	$ 89,229	$ 64,503
Cost of goods sold	(3,918)	(2,624)	(10,639)	(8,787)
Gross profit	31,184	17,939	78,590	55,716
Research and development expenses	11,011	7,986	31,215	19,875
Selling, general and administrative expenses	13,057	10,341	39,501	32,997
Total operating expenses	24,068	18,327	70,716	52,872
Operating income	7,116	(388)	7,874	2,844
Interest and other income	851	763	2,344	2,000
Income tax expense	1,015	(455)	1,668	248
Net income	$ 6,952	$ 830	$ 8,550	$ 4,596

Revenue

The increase in total revenue for the three and nine months ended September 30, 2026 compared to the same period in 2025 was due to the continued commercial expansion and demand of HEPZATO in the United States.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2026**	**2025**	**2026**	**2025**
CHEMOSAT	$ 2,426	$ 1,310	$ 6,145	$ 4,727
HEPZATO KIT	32,676	19,253	83,084	59,776
Total revenue	$ 35,102	$ 20,563	$ 89,229	$ 64,503

Our revenue is generated from a relatively concentrated group of customers. For the nine months ended September 30, 2026, two customers each accounted for more than 10% of our total product revenue, representing in the aggregate approximately 31.3% of revenue. For the nine months ended September 30, 2026, our largest customer represented 17.8% of revenue; as of September 30, 2026, that customer represented 15.9% of our total accounts receivable balance of $20.2 million. Our standard payment terms are 30 to 60 days, and we have not experienced material collection losses to date. However, as our commercial business scales, the absolute dollar concentration of our receivables with a limited number of large hospital or treatment center customers increases. A payment delay, dispute, or reduction in ordering activity by one or more significant customers could adversely affect our operating cash flow in any given period. We actively monitor our receivables aging and have not applied any estimated credit loss reserves against our accounts receivable balance as of September 30, 2026.

Cost of Goods Sold

The change in cost of goods sold for the three and nine months ended September 30, 2026 compared to the same period in 2025 is directly related to changes in demand for product revenue, offset by decreases in supplemental wages.

Research and Development Expenses

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Personnel Expenses	$ 4,970	$ 3,989	$ 14,994	$ 11,634
Trial and Research Expenses	5,428	3,667	14,463	7,564
Administrative and Other Expenses	613	330	1,758	677
	$ 11,011	$ 7,986	$ 31,215	$ 19,875

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 and nine months ended September 30, 2026 compared to the same period in 2025 is due to the continued costs associated with expanding the clinical team, including the base and supplemental wages related to an increase in headcount, and continuation of the Phase 2 clinical trials evaluating HEPZATO in combination with standard of care for mCRC and mBC. In addition to the Phase 2 clinical trials, we are researching initiatives to explore different indications, combinations, and potential applications of our therapies.

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 and nine months ended September 30, 2026 compared to the same period in 2025, selling, general and administrative expenses increased due to continued commercial expansion activities including marketing-related travel expenses and additional personnel on the commercial team.

Interest and other Income/Expense

Interest and other income is primarily related to the interest income associated with marketable securities and cash on hand. There was no interest expense for the three and nine months ended September 30, 2026 and 2025 due to all debt being paid off in 2024.

Liquidity and Capital Resources

Cash Flows

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

	Nine months ended September 30,	
	2026	2025
Net cash provided by operating activities	14,745	14,268
Net cash used in investing activities	(2,335)	(26,029)
Net cash (used in) provided by financing activities	(323)	20,992
Foreign currency effects on cash	(3)	170
	$ 12,084	$ 9,401

At September 30, 2026, we had cash and cash equivalents totaling $55.5 million and short-term investments totaling $48.8 million, as compared to cash and cash equivalents totaling $41.8 million and short-term investments totaling $47.1 million at September 30, 2025.

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 condensed consolidated financial statements. Our actual future liquidity and capital requirements will depend on numerous factors, including revenues recognized by us, 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 September 30, 2026, there have been 945,665 shares of common stock repurchased and retired under the repurchase program at an average price paid per share of $9.5085 for a total aggregate purchase price of approximately $9.0 million, which includes 628,572 shares repurchased prior to 2026 for an aggregate purchase price of approximately $6.0 million. We had approximately $16.0 million remaining under the share repurchase program at September 30, 2026.

Capital Commitments

Our capital commitments over the next twelve months include $13.0 million to satisfy accounts payable, accrued expenses, current lease liabilities and the current portion of the medac settlement. Additional capital commitments beyond the next twelve months include (a) $2.2 million of lease liabilities and (b) $0.3 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.

Critical Accounting Estimates

Management has completed its quarterly evaluation of estimates and 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 February 26, 2026.

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 our 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 September 30, 2026, the Company's Certifying Officers concluded that the Company's disclosure controls and procedures were effective.

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 September 30, 2026, 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 - "*Commitments 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 our Annual Report. 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.

We believe there have been no material changes in our risk factors from those disclosed in our Annual Report.

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

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 September 30, 2026, approximately $16.0 million remained available for repurchase by us under the stock repurchase authorization. There were no shares repurchased in the quarter ending September 30, 2026, as 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)
July 1, 2026 - July 31, 2026	—	—	—	$ 16,008
August 1, 2026 - August 31, 2026	—	—	—	$ 16,008
September 1, 2026 - September 30, 2026	—	—	—	$ 16,008
Total	—	$ —	—	

(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 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2026, 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 September 30, 2026 by our Section 16 officers or directors.

Item 6. Exhibits

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 13, 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 Current Report on Form 8-K filed on August 14, 2025).
31.1*	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.
31.2*	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.
32.1*+	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.
32.2*+	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.
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.

November 9, 2026 /s/ Gerard Michel

Gerard Michel

Chief Executive Officer
(Principal Executive Officer)

November 9, 2026 /s/ Sandra Pennell

Sandra Pennell

Chief Financial Officer
(Principal Financial and Accounting Officer)

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 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.

November 9, 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 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.

November 9, 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 Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended September 30, 2026, 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.

November 9, 2026

/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.

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 Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended September 30, 2026, 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.

November 9, 2026

/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.