Table of Contents

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 June 30, 2024
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)
(212) 489-2100
(Registrant's telephone number, including area code)

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

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

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 July 29, 2024, 27,999,522 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Table of Contents

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

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 14,782	$ 12,646
Restricted cash	—	50
Short-term investments	5,124	19,808
Accounts receivable, net	3,726	241
Inventory	6,316	3,322
Prepaid expenses and other current assets	1,451	1,091
Total current assets	31,399	37,158
Property, plant and equipment, net	1,422	1,352
Right-of-use assets	1,092	103
Total assets	$ 33,913	$ 38,613
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,279	$ 1,012
Accrued expenses	4,418	5,249
Lease liabilities, current	103	37
Loan payable	—	5,239
Convertible notes payable	4,491	4,911
Total current liabilities	12,291	16,448
Warrant liability	15,809	5,548
Lease Liabilities, non-current	989	—
Other liabilities, non-current	632	840
Total liabilities	29,721	22,836
Commitments and contingencies (see Note 14)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 12,342 and 24,819 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 27,931,393 shares and 22,761,554 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	279	228
Additional paid-in capital	533,919	520,576
Accumulated deficit	(530,014)	(505,162)
Accumulated other comprehensive loss	8	135
Total stockholders' equity	4,192	15,777
Total liabilities and stockholders' equity	$ 33,913	$ 38,613

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Product revenue	$ 7,766	$ 495	$ 10,905	$ 1,092
Total revenues	7,766	495	10,905	1,092
Cost of goods sold	(1,519)	(150)	(2,422)	(331)
Gross profit	6,247	345	8,483	761
Operating expenses:				
Research and development expenses	3,394	3,555	7,094	8,131
Selling, general and administrative expenses	6,765	4,787	15,579	8,952
Total operating expenses	10,159	8,342	22,673	17,083
Operating loss	(3,912)	(7,997)	(14,190)	(16,322)
Change in fair value of warrant liability	(9,755)	1,160	(10,367)	1,160
Interest expense, net	(84)	(371)	(283)	(1,059)
Other (expense) income	10	6	(12)	$ 19
Net loss	(13,741)	(7,202)	(24,852)	(16,202)
Other comprehensive (loss) income:				
Unrealized gain (loss) on investments	(141)	—	(133)	—
Foreign currency translation adjustments	(8)	—	6	19
Total comprehensive loss	$ (13,890)	$ (7,202)	$ (24,979)	$ (16,183)
Common share data:				
Basic and diluted loss per common share	$ (0.48)	$ (0.58)	$ (0.93)	$ (1.35)
Weighted average number of basic and diluted shares outstanding	28,364,731	12,463,665	26,625,955	12,035,738

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(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 (Loss)	Total
	No. of Shares	Amount	No. of Shares	Amount				
Balance at January 1, 2024	24,819	$ —	22,761,554	$ 228	$ 520,576	$ (505,162)	$ 135	$ 15,777
Compensation expense for issuance of stock options	—	—	—	—	2,895	—	—	2,895
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	50	—	—	50
Private placement -issuance of common shares, net of expenses	—	—	876,627	8	6,904	—	—	6,912
Issuance of common stock with the employee stock purchase plan	—	—	21,140	—	74	—	—	74
Conversion - F-3 Preferred to Common	(8,010)	—	1,779,998	18	(17)	—	—	1
Net loss	—	—	—	—	—	(11,111)	—	(11,111)
Unrealized gain on investments	—	—	—	—	—	—	8	8
Foreign currency translation adjustments	—	—	—	—	—	—	14	14
Balance at March 31, 2024	16,809	$ —	25,439,319	$ 254	$ 530,482	$ (516,273)	$ 157	$ 14,620
Compensation expense for issuance of stock options	—	—	—	—	3,021	—	—	3,021
Compensation expense for Employee Stock Purchase Plan	—	—	—	—	48	—	—	48
Prior quarter private placement - expenses	—	—	—	—	(141)	—	—	(141)
Warrant exercise and conversion - F-4 Preferred to Common	—	—	41,666	—	355	—	—	355
Conversion - F-3 Preferred to Common	(3,010)	—	668,888	7	(7)	—	—	—
Conversion - F-2 Preferred to Common	(1,457)	—	441,514	4	(4)	—	—	—
Pre-funded warrant exercise	—	—	1,307,706	13	(3)	—	—	10
Stock option exercise	—	—	32,300	1	168	—	—	169
Net loss	—	—	—	—	—	(13,741)	—	(13,741)
Unrealized loss on investments	—	—	—	—	—	—	(141)	(141)
Foreign currency translation adjustments	—	—	—	—	—	—	(8)	(8)
Balance at June 30, 2024	12,342	—	27,931,393	279	533,919	(530,014)	8	4,192

	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, 2023	11,357	$ —	10,046,571	$ 100	$ 451,608	$ (457,484)	$ (83)	$ (5,859)
Compensation expense for issuance of stock options	—	—	—	—	1,661	—	—	1,661
Private placement -issuance of common shares, net of expenses	—	—	19,646	1	55	—	—	56
Issuance of common stock with the employee stock purchase plan	—	—	15,417	—	47	—	—	47
Net loss	—	$ —	—	$ —	$ —	$ (9,000)	$ —	$ (9,000)
Foreign currency translation adjustments	—	—	—	—	—	—	19	19
Balance at March 31, 2023	11,357	$ —	10,081,634	$ 101	$ 453,371	$ (466,484)	$ (64)	$ (13,076)
Compensation expense for issuance of stock options	—	—	—	—	1,661	—	—	1,661
Conversion of Preferred F-1 shares to common shares	—	—	4,629,539	47	11,222	—	—	11,269
Preferred F-2 Shares Issuance	9,624	—	—	—	7,099	—	—	7,099
Pre-funded warrant exercise	—	—	538,828	5	—	—	—	5
Issuance of common stock related to stock option exercises	—	—	468	—	2	—	—	2
Net loss	—	—	—	—	—	(7,202)	—	(7,202)
Balance at June 30, 2023	20,981	—	15,250,469	153	473,355	(473,686)	(64)	(242)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	Six months ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (24,852)	$ (16,202)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	6,014	3,322
Depreciation expense	62	59
Warrant liability fair value adjustment	10,367	(1,160)
Non-cash lease expense	37	195
Amortization of debt discount	447	388
Interest expense accrued related to convertible notes	80	80
Amortization of premiums and discounts on marketable securities	(379)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(488)	(306)
Accounts receivable	(3,485)	239
Inventory	(2,994)	(482)
Accounts payable and accrued expenses	1,339	132
Other liabilities, non-current	(183)	(177)
Net cash used in operating activities	(14,035)	(13,912)
Cash flows from investing activities:		
Purchase of investment	(20,482)	—
Maturities of investments	35,540	—
Purchase of property, plant and equipment	(114)	(40)
Net cash provided by (used in) investing activities	14,944	(40)
Cash flows from financing activities:		
Net proceeds from private placement	6,771	22,960
Proceeds from the issuance of common stock relating to the employee stock purchase plan	75	47
Repayment of debt	(6,107)	(6,313)
Proceeds from exercise of warrants	259	5
Proceeds from exercise of stock options	169	2
Net cash provided by financing activities	1,167	16,701
Foreign currency effects on cash	10	19
Net increase in total cash	2,086	2,768
Total Cash, Cash Equivalents and Restricted Cash:		
Beginning of period	12,696	11,822
End of period	$ 14,782	$ 14,590
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash and Cash Equivalents	$ 14,782	$ 14,540
Restricted Cash	—	50
Total	$ 14,782	$ 14,590

	Six months ended June 30,	
	2024	2023
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 375	$ 787
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Right of use assets obtained in exchange for lease obligations	$ 1,029	$ 84
Conversion of mezzanine equity to common shares	$ —	$ 11,269
Conversion of mezzanine equity to preferred shares	$ —	$ 7,099

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 six months ended June 30, 2024 and 2023 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, 2023 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 26, 2024 and may also be found on the Company's website (www.delcath.com). In these notes to the interim condensed consolidated financial statements the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

The Company is an interventional oncology company focused on the treatment of cancers primary or metastatic to the liver. The Company's lead product, the HEPZATO™ KIT (melphalan for Injection/Hepatic Delivery System), a drug/device combination product, was approved by the US Food and Drug Administration (the "FDA") on August 14, 2023, indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection, or radiation. The first commercial use of HEPZATO KIT ("HEPZATO") 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 HEPZATO KIT to meet anticipated demand and it intends to manage supply chain risk through stockpiled inventory and, where commercially reasonable, contracting with multiple suppliers for critical components.

In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan ("CHEMOSAT"), where it has been used at major medical centers to treat a wide range of cancers in the liver. On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation (EU) 2017/745, which may be considered by jurisdictions when evaluating reimbursement.

To support the New Drug Application for HEPZATO the Company conducted the FOCUS Clinical Trial for Patients with metastatic hepatic dominant Uveal Melanoma (the "FOCUS Trial"), a global registration clinical trial that investigated objective response rate in patients with mUM. On May 6, 2024, the Company announced the publication of results from the pivotal FOCUS Trial in the journal Annals of Surgical Oncology. The current focus of the Company's clinical development program is to generate clinical data for CHEMOSAT and HEPZATO either as monotherapy or in combination with immunotherapy. The Company expects that this will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support reimbursement in various jurisdictions, including the United States. In addition to HEPZATO's use to treat mUM, the Company believes that HEPZATO has the potential to treat other cancers in the liver, such as metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic breast cancer and intrahepatic cholangiocarcinoma, and plans to begin one or more studies of HEPZATO KIT to treat such conditions in late 2024 or early 2025. The Company believes that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

Risks and Uncertainties

As detailed in the Company's 2023 Annual Report filed on Form 10-K, the Company is subject to risks common to companies in the biopharmaceutical industry with FDA-approved products and planned clinical development activities, including, but not limited to, risks associated with successfully launching and commercializing the products; further developing HEPZATO to potentially treat other cancers in the liver and the Company's ability to obtain any additional regulatory approval of such products in the United States and obtaining regulatory approval in other geographic markets;

the uncertainty relating to the broad adoption of any approved products by physicians and consumers; and the impacts of significant competition.

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

Liquidity and Going Concern

On June 30, 2024, the Company had cash and cash equivalents totaling $14.8 million and short-term investments totaling $5.1 million, as compared to cash, cash equivalents and restricted cash totaling $12.7 million and short-term investments totaling $19.8 million at December 31, 2023. During the six months ended June 30, 2024, the Company used $14.0 million of cash in its operating activities and $6.1 million for principal payments.

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

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

The Company expects to use cash and cash equivalents to fund activities relating to commercial support for HEPZATO, CHEMOSAT and any future clinical research trials and operating activities. The Company's future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining regulatory approvals and complying with applicable laws and regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; the resolution of any disputes with third parties; and the effect of competing technological and market developments.

The Company's capital commitments over the next twelve months include (a) $7.8 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement and (b) $4.5 million of loan and convertible note principal payments, if the holders do not elect to convert the notes into equity. Additional capital commitments beyond the next twelve months include (a) $1.4 million of lease liabilities; and (b) $0.6 million for settlement of litigation with medac.

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 June 30, 2024 and 2023; however, certain information and footnote disclosures normally included in our audited consolidated financial statements which were included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

There have been no material changes to our significant accounting policies as set forth in Note 3 Summary of Significant Accounting Policies to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Recent Accounting Pronouncements

No new accounting standards were adopted during the six months ended June 30, 2024.

(2) Revenue

The Company recognizes product revenue from sales of HEPZATO in the United States and CHEMOSAT in certain European countries in accordance with the five-step model in Accounting Standards Codification ("ASC") 606, Revenue Recognition: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation. Under this revenue standard, the Company recognizes revenue when its customer obtains control of the promised goods, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods. There are no contractual rights of returns, refunds or similar obligations.

HEPZATO

The Company ships and sells the HEPZATO directly to hospitals and treating centers based on approved agreements. Prior to use of the HEPZATO, the inventory is considered on consignment in which the Company retains title to the product. The Company recognizes HEPZATO revenue, based on contracted rates stated in an approved contract or purchase order, upon completion of the procedure as evidenced through the Company's required Risk Evaluation and Mitigation Strategy ("REMS") system. There is no obligation for the hospitals or treating centers to use the consigned HEPZATO, and the Company has no contractual right to receive payment until the product is used in a procedure and transfer of control is completed. See Note 4 for further information for consignment inventory.

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 June 30,		Six Months Ended June 30,	
(In thousands)	**2024**	**2023**	**2024**	**2023**
CHEMOSAT	$ 1,196	$ 495	$ 2,327	$ 1,092
HEPZATO KIT	6,570	—	8,578	—
Total revenue	$ 7,766	$ 495	$ 10,905	$ 1,092

Concentration of Credit Risk

Potential credit risk exposure for both 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 June 30, 2024, there were no estimated losses applied to the accounts receivables balance.

The Company's total percentage of revenue and accounts receivable concentrations from a single customer consisted of the following:

For the six months ended and as of	Revenue	Accounts Receivable
June 30, 2024	52.0 %	34.0 %
June 30, 2023	19.0 %	36.8 %

(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 June 30, 2024:

	June 30, 2024		
		Gross Unrealized	
(In thousands)	Amortized Cost	Gains	Estimated Fair Value
U.S. government agency bonds	$ 5,100	$ 24	$ 5,124
Short-term investments			$ 5,124

As of June 30, 2024, there was less than $0.1 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, 2023:

	December 31, 2023		
		Gross Unrealized	
(in thousands)	Amortized Cost	Gains	Estimated Fair Value
U.S. government agency bonds	$ 19,651	$ 157	$ 19,808
Short-term investments			$ 19,808

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

(4) Inventory

Inventory consists of the following:

(In thousands)	June 30, 2024	December 31, 2023
Raw materials	$ 3,590	$ 1,443
Work-in-process	2,162	1,753
Finished goods	564	126
Total inventory	$ 6,316	$ 3,322

The Company has consignment agreements with approved hospitals and treatment centers. As of June 30, 2024, there was $0.3 million in finished goods held at hospitals and treatment centers.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(In thousands)	June 30, 2024	December 31, 2023
Clinical trial expenses	$ 222	$ 222
Insurance premiums	145	157
Professional services	657	133
Interest Receivable	23	151
Other	404	428
Total prepaid expenses and other current assets	$ 1,451	$ 1,091

(6) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(In thousands)	June 30, 2024	December 31, 2023	Estimated Useful Life
Buildings and land	$ 1,318	$ 1,318	30 years - Buildings
Enterprise hardware and software	1,855	1,857	3 years
Leaseholds	1,776	1,787	Lesser of lease term or estimated useful life
Equipment	1,348	1,263	7 years
Furniture	238	202	5 years
Construction in process	10	—	
Property, plant and equipment, gross	6,545	6,427	
Accumulated depreciation	(5,123)	(5,075)	
Property, plant and equipment, net	$ 1,422	$ 1,352	

Depreciation expense for the three and six months ended June 30, 2024 and 2023 was less than $0.1 million for each period.

(7) Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	June 30, 2024	December 31, 2023
Clinical expenses	$ 419	$ 1,129
Compensation, excluding taxes	2,302	1,859
Professional fees	165	272
Interest on convertible note	793	713
Inventory	8	585
Other	731	691
Total accrued expenses	$ 4,418	$ 5,249

(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 both the three months ended June 30, 2024 and 2023, the Company recognized less than $0.1 million of operating lease expense, and $0.1 million and $0.2 million for the six months ended June 30, 2024 and 2023, respectively.

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.

In 2020, the Company entered into an amendment to a sub-lease agreement executed in 2016 for office space at 1633 Broadway, New York, New York. The term of the sub-lease agreement began in April 2016 and, pursuant to amendments, was extended through August 2023. As of August 31, 2023, the lease was month-to-month. No ROU assets or lease liabilities were recognized on the balance sheet as of December 31, 2023 for this arrangement. The Company ended the sublease for its former corporate offices at 1633 Broadway, New York, New York in February 2024.

On January 18, 2024, the Company entered into a lease agreement (the "Queensbury Lease") to lease approximately 18,000 square feet of manufacturing and office space in Queensbury, New York (the "Premises"). The initial term of the lease is five years with a right to extend the lease by an additional five years, exercisable under certain conditions set forth in the Queensbury Lease. The Company's annual rent expense under the Queensbury Lease is less than $0.2 million for a term of 5 years.

The following table summarizes the Company's operating leases as of June 30, 2024:

(In thousands)	U.S.	Ireland	Total
Operating lease cost	20	17	37
Operating cash flows for operating leases	$ (40)	$ (21)	$ (61)
Weighted average remaining lease term	9.6	2.1	
Weighted average discount rate - operating leases	8 %	8 %	

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

(In thousands)	U.S.	Ireland	Total
Year ended December 31, 2024	$ 72	$ 21	$ 93
Year ended December 31, 2025	144	43	187
Year ended December 31, 2026	144	25	169
Year ended December 31, 2027	148	—	148
Year ended December 31, 2028	153	—	153
Thereafter	800	—	800
Total	1,461	89	1,550
Less present value discount	(451)	(7)	(458)
Operating lease liabilities included in the condensed consolidated balance sheets at June 30, 2024	$ 1,010	$ 82	$ 1,092

(9) Loans and Convertible Notes Payable

	June 30, 2024			December 31, 2023		
(In thousands)	Gross	Discount	Net	Gross	Discount	Net
Loans payable, current	$ —	$ —	$ —	$ 5,610	$ (371)	$ 5,239
Convertible notes payable - current[1]	4,503	(12)	4,491	5,000	(89)	4,911
Total - Loans and notes payable	$ 4,503	$ (12)	$ 4,491	$ 10,610	$ (460)	$ 10,150

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

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

On August 6, 2021, the Company entered into a Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue") for a term loan in an aggregate principal amount of up to $20.0 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.70% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at June 30, 2024 was 16.20%.

The Avenue Loan Agreement requires the Company to make and maintain representations and warranties and other agreements that are customary in loan agreements of this type. The Avenue Loan Agreement also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy and material judgements. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property.

The initial tranche of the Avenue Loan was $15.0 million, including $4.0 million that was funded into a restricted account. On March 15, 2023, the Company returned to Avenue $4.0 million held as restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, the Avenue Loan Agreement was amended (the "Avenue Amendment") to defer the interest only period to September 30, 2023, with an additional extension option upon FDA Approval for the HEPZATO KIT and subsequent receipt of at least $10 million from the sale and issuance of equity securities. On August 14, 2023, the Company received FDA approval and has subsequently received over $10 million from the exercise of Tranche A Preferred Warrants. At the Company's option, it elected to extend the interest only period to December 31, 2023 and monthly principal payments of approximately $1.0 million began in January 2024 with the final payment occurring on August 1, 2024.

The remaining principal amount of the Avenue Loan outstanding of $2.5 million at June 30, 2024 could be converted, at Avenue's option, into shares of the Company's common stock at a conversion price of $11.98 per share.

Avenue did not exercise its option to convert the remaining principal amount of the Avenue Loan into shares of the Company's common stock and on August 1, 2024, the Company made the final payment due on the Avenue Loan. The Company is anticipating the release from all obligations and Avenue to return all security interests back to the Company.

In connection with the initial entry into the Avenue Loan Agreement, the Company issued warrants to Avenue (the "Initial Avenue Warrant") to purchase 127,755 shares of common stock at an exercise price per share equal to $0.01. Additionally, in connection with the Avenue Amendment, the Company issued to Avenue a warrant to purchase 34,072 shares of common stock at an exercise price per share equal to $0.01. Avenue exercised all outstanding warrants connected to the Avenue Loan in full in April 2024.

The Company determined that the embedded conversion option associated with the Avenue Loan did not require bifurcation and met the criteria for equity classification. In addition, the amendment was recorded under debt modification guidance. Aggregate debt discount amortization of $0.2 million was recorded during both the three months ended June 30, 2024 and 2023, and $0.4 million for both the six months ended June 30, 2024 and 2023. Interest expense incurred was $0.1 million and $0.3 million for the three months ended June 30, 2024 and 2023, respectively, and $0.4 million and $0.8 million for the six months ended June 30, 2024 and 2023, respectively.

Convertible Notes Payable

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

On August 6, 2021, the Company executed an agreement to amend the Rosalind Notes to (i) reduce the conversion price to $1,198 per share of the Company's Series E Preferred Stock; and (ii) extend the maturity date to October 30, 2024. In addition, the holders of the Rosalind Notes agreed to subordinate all of the Company's indebtedness and obligations to Avenue and all of the holders' security interest to the Avenue Loan and Avenue's security interest in the Company's property.

Interest expense accrued relating to the Rosalind Notes was less than $0.1 million for both the three and six months ended June 30, 2024 and 2023.

(10) Preferred Purchase Agreement

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

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

As of June 30, 2024, all of the Preferred Tranche A Warrants were exercised for an aggregate exercise price of $34.9 million and 250 Preferred Tranche B Warrants were exercised for an aggregate exercise price of $0.3 million. The remaining Preferred Tranche B Warrants are exercisable for 24,650 shares of Series F-4 Preferred Stock, with an aggregate exercise price of $24.7 million until the earlier of (i) 21 days following the Company's announcement of receipt of at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO and (ii) March 31, 2026.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series F-1 Preferred Stock automatically converted into shares of common stock and/or, if applicable (in accordance with the beneficial ownership limitations then in effect), shares of Series F-2 Preferred Stock, par value $0.01 per share (the "Series F-2 Preferred Stock" and, together with the Series F-1 Preferred Stock, the Series F-3 Preferred Stock and the Series F-4 Preferred Stock, the "Series F Preferred Stock") in lieu of common stock. Subject to limitations set forth in the Certificate of Designation, the shares of Series F-2, F-3 and F-4 Preferred Stock are convertible into common stock at the option of the holder at the conversion price of $3.30 per share, $4.50 per share and $6.00 per share, respectively, rounded down to the nearest whole share, and in each case subject to the terms and limitations contained in the Certificate of Designation.

As of June 30, 2024, 58,924 shares of the Company's Series F-1, F-2, F-3 and F-4 Preferred Stock were converted into 15,005,211 shares of common stock. As of June 30, 2024, there were 1,085 shares of Series F-2 Preferred Stock, and no shares of Series F-3 Preferred Stock or Series F-4 Preferred Stock outstanding.

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

The Company determined that the outstanding Preferred Warrants should be liability-classified. See Note 15 for a discussion of the accounting treatment of the Common Warrants and Preferred Warrants.

(11) Stockholders' Equity

Public and Private Placements

Common Purchase Agreement

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

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

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

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

Securities Purchase Agreement

On March 14, 2024, the Company and certain accredited investors (each an "Investor" and collectively, the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company agreed to sell and issue to the Investors in a private placement (the "Private Placement") (i) an aggregate of 876,627 shares of the Company's common stock, par value $0.01 per share, at a purchase price of $3.72 per share, and (ii) to certain investors, in lieu of shares of common stock, 1,008,102 pre-funded warrants (the "Pre-Funded Warrants") at a price per Pre-Funded Warrant of $3.71 (the "Warrant Shares" and together with the Shares, the "Securities") with an exercise price of $0.01. As of June 30, 2024 the Pre-Funded Warrants have been exercised in full.

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

Registration Rights for Preferred and Common Offerings

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

Pursuant to the Securities Purchase Agreement, the Company filed a registration statement on Form S-3 (the "April 2024 Resale Registration Statement") providing for the resale of the common stock and common stock issuable upon the exercise of the Pre-Funded Warrants. The April 2024 Resale Registration Statement also provided for the common stock issued upon the exercise of pre-funded warrants to purchase common stock issued by the Company pursuant to the Avenue Amendment. The registration became effective on May 9, 2024.

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

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.

At-the-Market Offering

The Company previously entered into a Controlled Equity Offering^{SM} Sales Agreement ("ATM Sales Agreement"), with Cantor Fitzgerald & Co. (the "Sales Agent"), pursuant to which the Company may offer and sell, at its sole discretion through the Sales Agent, shares of its common stock from time to time. Pursuant to a prospectus supplement (the "ATM Prospectus Supplement"), filed with the SEC on February 27, 2023, the Company could sell shares of common stock under the ATM Sales Agreement up to an aggregate of $17.0 million. To date, the Company has sold approximately $4.0 million of its common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the three or six months ended June 30, 2024.

The registration statement of which the ATM Prospectus Supplement forms a part expired on July 1, 2024 and the Company can no longer make sales under the ATM Prospectus Supplement. The Company may file a new prospectus supplement with respect to the ATM Sales Agreement, or with respect to a similar arrangement, in the future.

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 June 30, 2024, the Company has designated the following preferred stock:

Designated Preferred Shares	June 30, 2024
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 June 30, 2024, there were an aggregate of 11,257 shares of Series E and Series E-1, 1,085 Series F-2 and no shares of Series F-3 or Series F-4 Convertible Preferred Stock outstanding, respectively.

Omnibus Equity Incentive Plan

On September 30, 2020, the Company's 2020 Omnibus Equity Incentive Plan (the "2020 Plan") was adopted by the Company's Board of Directors. On November 23, 2020, the Company's stockholders approved the 2020 Plan. The 2020 Plan will continue in effect until the tenth anniversary of the date of its adoption by the Board or until earlier terminated by the Board. The 2020 Plan is administered by the Board of Directors or a committee designated by the Board of Directors. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed to be consistent with the purposes of the plan to Company employees, directors and consultants. As of June 30, 2024, there have been 7,125,000 shares of common stock reserved under the 2020 Plan, which includes an additional 2,000,000 shares approved by shareholders on May 23, 2024 and registered on a Form S-8 registration statement, filed with the SEC on June 28, 2024, of which 2,140,327 remained available to be issued.

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

On December 5, 2023, the Company's 2023 Inducement Plan (the "2023 Plan") was adopted by the Company's Board of Directors. The 2023 Plan is administered by a Compensation Committee of two or more Independent Directors appointed by the Board of Directors and is intended to provide for the grant of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed appropriate to incentivize employment with the Company. Awards from the 2023 Plan can only be granted to individuals who have not previously worked for the Company or have not worked for the Company for a bona fide period of time. As of June 30, 2024, there have been 650,000 shares of common stock reserved under the 2023 Plan, of which 339,000 remain available to be granted.

Stock Options

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

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

	Six Months Ended June 30,	
	2024	2023
Expected terms (years)	5.5	5.7
Expected volatility	114.3%	161.6%
Risk-free interest rate	4.22%	3.94%
Expected dividends	0.00%	0.00%

The following is a summary of stock option activity for the six months ended June 30, 2024:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2024	4,183,232	$ 8.17	$ 7.60	8.3	$ 147
Granted	2,213,096	5.01	4.09	9.5	
Exercised	(32,300)	5.22	4.15		60
Expired	(46,956)	8.63	8.34		
Cancelled/Forfeited	(184,958)	5.88	5.49		
Outstanding at June 30, 2024	6,132,114	$ 7.11	$ 6.41	8.4	$ 12,902
Exercisable at June 30, 2024	2,995,121	$ 8.95	$ 8.17	7.4	$ 3,443
Unvested at June 30, 2024	3,136,993	$ 5.36	$ 4.73	9.3	$ 9,459

The following table summarizes information for stock option shares outstanding and exercisable at June 30, 2024:

		Options Outstanding	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
$2.83 - $51.50	6,131,615	8.4	6,131,615
$51.50+	499	3.8	499
	6,132,114	8.4	6,132,114

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2024	2023	2024	2023
Selling, general and administrative	$ 1,930	$ 911	$ 3,971	$ 2,099
Research and development	895	651	1,543	1,068
Cost of goods sold	244	99	500	155
Total	$ 3,069	$ 1,661	$ 6,014	$ 3,322

At June 30, 2024, there was $8.3 million of aggregate unrecognized compensation expense related employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 1.1 years.

Common Stock Warrants

The following is a summary of common stock warrant activity for the six months ended June 30, 2024:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2024	4,665,201	$ 7.76	1.6
Warrants issued[1]	1,008,102	0.01	
Warrants exercised	(1,308,473)	0.01	
Outstanding and exercisable at June 30, 2024	4,364,830		1.1

[1]All warrants issued in 2024 have been exercised and therefore have no remaining life.

The following table presents information related to common stock warrants outstanding at June 30, 2024:

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$0.01	737,421	3.1	737,421
$6.00	16,666	1.8	16,666
$10.00	3,610,743	0.7	3,610,743
	4,364,830	1.1	4,364,830

Preferred Stock Warrants

The following is a summary of preferred stock warrant activity for the six months ended June 30, 2024:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2024	24,900	$ 1,000	2.3
Warrants issued	—		
Warrants exercised	(250)	1,000	
Outstanding and exercisable at June 30, 2024	24,650	$ 1,000	1.8

Employee Stock Purchase Plan

In August 2021, the Company's Board of Directors, with shareholder approval in May 2022, adopted the Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for a maximum of 260,295 shares of common stock to be purchased by participating employees of which 62,575 have been issued as of June 30, 2024 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.

(12) Net Loss per Share

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

The following potentially dilutive securities were excluded from the computation of earnings per share as of June 30, 2024 and 2023 because their effects would be anti-dilutive:

	June 30,	
	2024	2023
Common stock warrants	3,627,409	3,658,520
Assumed conversion of preferred stock warrants	4,108,328	11,896,667
Assumed conversion of preferred stock	1,454,509	4,051,637
Assumed conversion of convertible notes	446,563	488,031
Stock options	6,132,114	4,127,932
Total	15,768,923	24,222,787

As of June 30, 2024 and 2023, the Company had 737,421 and 1,037,792 pre-funded warrants outstanding, respectively. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three and six months ended June 30, 2024 and 2023:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Weighted average shares issued	27,317,256	11,320,450	25,511,315	10,693,762
Weighted average pre-funded warrants	1,047,475	1,143,215	1,114,640	1,341,976
Weighted average shares outstanding	28,364,731	12,463,665	26,625,955	12,035,738

(13) Income Taxes

As discussed in “Note 17—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 17 - Income Taxes of the Company’s Annual Report.

The Inflation Reduction Act of 2022 included tax legislation that became effective in the first quarter of 2023. Significant legislation for corporate taxpayers includes a corporate alternative minimum tax of 15% for companies with $1 billion or more in average net financial statement profits over the three previous years, as well as a 1% indirect excise tax on the repurchase of shares by a publicly traded company. The Company does not expect this legislation to have an effect on the tax provision as of June 30, 2024, however the Company will continue to evaluate the effect on the tax provision each reporting period.

(14) 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 first annual payment was made in May 2024 and the Company has estimated the remaining fair value of the settlement to be $0.8 million as of June 30, 2024 and recorded $0.6 million as other liabilities, non-current and $0.2 million as accrued expenses on the Company's condensed consolidated balance sheet as of June 30, 2024.

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 June 30, 2024, the Company has committed to purchase $2.4 million of melphalan under this Supply Agreement in 2024.

(15) Fair Value Measurements

The table below presents activity within Level 3 of the fair value hierarchy, our liabilities carried at fair value for the six months ended June 30, 2024:

	Level 3		
(In thousands)	**Contingent liabilities**	**Warrants**	**Total**
Balance at January 1, 2024	$ 996	$ 5,548	$ 6,544
Total change in foreign exchange	(25)	—	(25)
Warrant liability fair value adjustment	—	10,367	10,367
Change due to warrant exercise	—	(106)	(106)
Change due to liability payment	(221)	—	(221)
Balance at June 30, 2024	$ 750	$ 15,809	$ 16,559

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

As disclosed in Note 10 and Note 11 of the Company's consolidated financial statements, the Company allocated part of the proceeds of the Series F Preferred Offering to warrant liability issued in connection with the transaction. The valuations of the warrants were determined using option pricing models. The Company concluded that the Preferred Warrants were not in the scope of Accounting Standards Codification, Distinguishing Liabilities from Equity (ASC 480) since the Preferred Warrants are not mandatorily redeemable; and do not have obligations to issue a variable number of shares of preferred stock. The Company determined the Preferred Warrants met the definition of a derivative in accordance with ASC 815 but were not considered indexed to the Company's common stock since the warrants require early settlement by repurchasing the preferred warrants for cash in an amount equal to the Black-Scholes value in the event of a Fundamental Transaction at pre-specified volatility of 100% as an input to the Black-Scholes calculation. The Company determined to record the Preferred Warrants at fair value with subsequent changes in fair value recorded in earnings at the end of each reporting period. For the three and six months ended June 30, 2024, the Company recorded an increase to other expense of $9.8 million and $10.4 million, respectively, related to the change in fair value of the warrant liability. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the warrants as a long-term liability due to potential provisions relating to the holders' ability to exercise the warrants beyond twelve months of the reporting date.

The fair value of the preferred and common warrants at June 30, 2024 and December 31, 2023 was determined by using option pricing models assuming the following:

	June 30, 2024	December 31, 2023
Risk free interest rate	4.69%	4.09%
Expected term (years)	1.8	2.3
Expected volatility	60%	70%
Expected dividends	0.00%	0.00%

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

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value as of June 30, 2024 and December 31, 2023 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value.

	June 30, 2024			
(In thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 5,466	$ —	$ —	$ 5,466
U.S. government agency bonds	—	5,124	—	5,124
Total Assets	$ 5,466	$ 5,124	$ —	$ 10,590
Liabilities:				
Contingent Liability	$ —	$ —	$ 750	$ 750
Warrant Liabilities	—	—	15,809	15,809
Total Liabilities	$ —	$ —	$ 16,559	$ 16,559

(In thousands)	December 31, 2023			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 392	$ —	$ —	$ 392
U.S. government agency bonds	—	19,808	—	19,808
Total Assets	$ 392	$ 19,808	$ —	$ 20,200
Liabilities:				
Contingent Liability	$ —	$ —	$ 996	$ 996
Warrant Liabilities	—	—	5,548	5,548
Total Liabilities	$ —	$ —	$ 6,544	$ 6,544

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, 2023 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 26, 2024, to provide an understanding of its results of operations, financial condition and cash flows.

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

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

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity, and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended (the "Securities Act"). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in Item 3 "Quantitative and Qualitative Disclosures About Market Risk," and the risks discussed in Part II, Item 1A under "Risk Factors" and the risks detailed from time to time in our future reports filed with the SEC. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements, future revenue and our need for additional financing;
- the commencement of future clinical trials, if any, and the results and timing of those clinical trials;
- our expectations that the publication of additional data from our Phase 3 FOCUS Trial will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and support reimbursement in various jurisdictions, including the United States;
- our ability to successfully commercialize CHEMOSAT, HEPZATO, and future products, if any, generate revenue and successfully obtain reimbursement for the products and/or the associated procedures;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of CHEMOSAT, HEPZATO, and future products, if any;
- the rate and degree of market acceptance and clinical utility of CHEMOSAT, HEPZATO, and future products, if any;
- developments relating to our competitors and our industry;
- the initiation and success of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source components of CHEMOSAT, HEPZATO, and future products, if any, and enter into supplier contracts;
- our ability to source melphalan and other critical components necessary to manufacture HEPZATO;

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

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this 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 primary cancers metastatic to the liver. Our lead product, the HEPZATO KIT (melphalan for Injection/Hepatic Delivery System), a drug/device combination product, was approved by the US Food and Drug Administration (the "FDA") on August 14, 2023, indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection, or radiation. The first commercial use of HEPZATO for the treatment of metastatic hepatic dominant uveal melanoma ("mUM") took place in January 2024.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted us six orphan drug designations (five for melphalan in the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma).

We have sufficient raw material and component constituent parts of HEPZATO KIT to meet anticipated demand and we intend to manage supply chain risk through stockpiled inventory and contracting with multiple suppliers for critical components. As of July 31, 2024, eight facilities have treated at least one patient with the HEPZATO KIT.

In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers in the liver. On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation (EU)2017/745, which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Our clinical development program for HEPZATO was comprised of the FOCUS Clinical Trial for Patients with metastatic hepatic dominant Uveal Melanoma (the "FOCUS Trial"), a global registration clinical trial that investigated objective response rate in patients with mUM. The current focus of our clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in patients with mUM, either as monotherapy or in combination with immunotherapy. On May 6, 2024, we announced the publication of results from our Phase 3 FOCUS Trial, including an Overall Response Rate ("ORR") of 36.35, which included 7.7% of patients with Complete Response, as determined by an Independent Review Committee. An ORR of 36.3% in the FOCUS study was statistically significantly better than the pooled ORR estimate (a weighted mean of the observed ORR) of 5.5% in the historical control group. We expect that the publication will support increased clinical adoption of and reimbursement for CHEMOSAT in Europe, and support reimbursement in various jurisdictions, including the United States.

In addition to HEPZATO's use to treat mUM, the Company believes that HEPZATO has the potential to treat other cancers in the liver, such as metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic breast cancer and intrahepatic cholangiocarcinoma, and plans to begin one or more studies of HEPZATO KIT to treat such conditions in late 2024 or early 2025. We believe that those and similar disease states are areas of unmet medical needs that represent significant market opportunities.

Results of Operations

(In thousands)	Three months ended June 30, 2024	Three months ended June 30, 2023	Six months ended June 30, 2024	Six months ended June 30, 2023
Total revenues	$ 7,766	$ 495	$ 10,905	$ 1,092
Cost of goods sold	(1,519)	(150)	(2,422)	(331)
Gross profit	6,247	345	8,483	761
Research and development expenses	3,394	3,555	7,094	8,131
Selling, general and administrative expenses	6,765	4,787	15,579	8,952
Total operating expenses	10,159	8,342	22,673	17,083
Operating loss	(3,912)	(7,997)	(14,190)	(16,322)
Interest and other income (expense)	(9,829)	795	(10,662)	120
Net loss	$ (13,741)	$ (7,202)	$ (24,852)	$ (16,202)

Revenue

The increase in total revenue for the three and six months ended June 30, 2024 compared to the same periods in 2023 was due to the commercial launch of HEPZATO KIT in the U.S. along with an increase in demand for CHEMOSAT in Europe.

Cost of Goods Sold

The change in cost of goods sold for the three and six months ended June 30, 2024 compared to the same periods in 2023 is directly related to changes in demand for product revenue.

Research and Development Expenses

Research and development expenses are incurred for the development of HEPZATO and consist primarily of payroll and payments to contract research and development companies. In 2023, these costs primarily related to generating pre-clinical data submission of the NDA and the cost of manufacturing HEPZATO for expanded access protocol sites utilizing HEPZATO KIT prior to FDA approval. The decrease for the three and six months ended June 30, 2024 compared to the same period in 2023 is due to lower costs associated with NDA submission offset by an increase in medical affairs and regulatory costs associated with an approved product.

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 six months ended June 30, 2024 compared to the same periods in 2023, selling, general and administrative expenses increased due to activities supporting the commercial launch of HEPZATO.

Interest and other Income/Expense

Interest and other income (expense) in 2024 is primarily related to the change in fair value of the Tranche B Warrants liability, interest income associated with marketable securities offset by interest expense related to our debt instruments. There was a decrease in interest expense for the three and six months ended June 30, 2024 compared to the same periods in 2023 related to the principal loan payments made during 2023 and 2024.

Liquidity and Capital Resources

At June 30, 2024, we had cash and cash equivalents totaling $14.8 million and short-term investments totaling $5.1 million, as compared to cash, cash equivalents and restricted cash totaling $12.7 million and short-term investments totaling $19.8 million at December 31, 2023. During the six months ended June 30, 2024, we used $14.0 million of cash for operating activities compared to $13.9 million during the six months ended June 30, 2023, and $6.1 million for principal payments during the six months ended June 30, 2024, compared to $6.3 million for principal payments during the six months ended June 30, 2023. At June 30, 2023, we had cash, cash equivalents and restricted cash totaling $14.6 million.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve or maintain profitability. We have historically funded our operations primarily with

proceeds from sales of common stock, warrants and pre-funded warrants for the purchase of common stock, sales of preferred stock, proceeds from the issuance of convertible debt and borrowings under loan and security agreements.

Funding Requirements

If there is a substantial delay in the activation of additional sites to administer HEPZATO and/or the revenue generated from HEPZATO and CHEMOSAT is less than anticipated, we expect to need to raise additional capital under structures available to us, including debt and/or equity offerings, which may not be on terms favorable to us. In a substantially delayed site activation scenario, we will not have sufficient funds to meet our obligations within twelve months from the issuance date of these condensed consolidated financial statements. As such, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs for product candidates and/or grant licenses on terms that may not be favorable to us, any of which may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates to third parties even if we would otherwise prefer to develop and market such product candidates ourselves.

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

Capital Commitments

Our capital commitments over the next twelve months include (a) $7.8 million to satisfy accounts payable, accrued expenses, current lease liabilities and current medac settlement and (b) $4.5 million of loan and convertible note principal payments, if the holders do not elect to convert the notes into equity. Additional capital commitments beyond the next twelve months include (a) $1.4 million of lease liabilities and (b) $0.6 million for settlement of litigation with medac.

Source 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.

At-the-Market Offering

We previously entered into a Controlled Equity Offering℠ Sales Agreement ("ATM Sales Agreement"), with Cantor Fitzgerald & Co. (the "Sales Agent"), pursuant to which we may offer and sell, at our sole discretion through the Sales Agent, shares of our common stock from time to time. Pursuant to a prospectus supplement (the "ATM Prospectus Supplement"), filed with the SEC on February 27, 2023, we could sell shares of common stock under the ATM Sales Agreement up to an aggregate of $17.0 million. To date, we have sold approximately $4.0 million of our common stock, prior to issuance costs, under the ATM Sales Agreement. No sales were made during the three and six months ended June 30, 2024.

The registration statement of which the ATM Prospectus Supplement forms a part expired on July 1, 2024 and we can no longer make sales under the ATM Prospectus Supplement. We may file a new prospectus supplement with respect to the ATM Sales Agreement, or with respect to a similar arrangement, in the future.

Avenue Loan Agreement

On August 6, 2021, we entered into the Avenue Loan Agreement with Avenue Venture Opportunities Fund, L.P. (the "Lender," or "Avenue"), as amended on March 31, 2023, for a term loan in an aggregate principal amount of up to $20 million (the "Avenue Loan"). The Avenue Loan bears interest at an annual rate equal to the greater of (a) the sum of 7.7% plus the prime rate as reported in The Wall Street Journal and (b) 10.95%. The interest rate at June 30, 2024 was 16.20%. The Avenue Loan is secured by all of our assets globally, including intellectual property. On March 15, 2023, we returned to Avenue $4.0 million held in the restricted cash to pay down a portion of the outstanding loan balance, principal payments of $2.1 million and an incremental 4.25% of the final payment of $0.2 million. On March 31, 2023, we reached an agreement to amend the existing loan agreement with Avenue to defer the interest only period to September 30, 2023, with an additional extension option upon the FDA approval for HEPZATO KIT and subsequent receipt of at least $10 million from the sale and issuance of equity securities. In exchange for this extension, we agreed to provide Avenue with 34,072 warrants to purchase shares of common stock at an exercise price of $0.01 per warrant share, all of which were exercised in April 2024. On August 14, 2023, we received the FDA approval for the HEPZATO KIT and subsequently received over $10 million from the exercise of warrants. At our option, we elected to extend the interest only period to December 31, 2023. Principal payments of approximately $1.0 million began in January 2024.

The remaining principal amount of the Avenue Loan outstanding of $2.5 million at June 30, 2024 could be converted, at Avenue's option, into shares of our common stock at a conversion price of $11.98 per share.

Avenue did not exercise its option to convert the remaining principal amount of the Avenue Loan into shares of our common stock and on August 1, 2024, we made the final payment due on the Avenue Loan. We are anticipating the release from all obligations and Avenue to return all security interests back to us.

Private Placements, Common Offering and Warrants

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

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

On June 12, 2023, the stockholders approved the Private Placements at the annual general meeting of stockholders and therefore, the Preferred Warrants and Common Warrants issued in the Private Placements are exercisable. The exercise of all such Preferred Warrants and Common Warrants would generate approximately $60.0 million in proceeds. There can be no guarantee that all such Warrants are ever exercised, and if so, there is no guarantee that we will ever receive the full $60.0 million in proceeds. As of June 30, 2024, all of the Preferred Tranche A Warrants were exercised for an aggregate exercise price of $34.9 million into 34,859 shares of Series F-3 Preferred Stock, 250 shares Preferred Tranche B Warrants were exercised for an aggregate exercise price of $0.3 million and all of the Common Tranche A Warrants were exercised for an aggregate exercise price of $0.1 million into 31,110 shares of common stock.

As of June 30, 2024, 58,924 shares of our Series F-1, F-2, F-3 and F-4 Preferred Stock were converted into 15,005,211 shares of common stock.

On March 14, 2024, we and certain accredited investors (each an "Investor" and collectively, the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which we agreed to sell and issue to the Investors in a private placement (the "Private Placement") (i) an aggregate of 876,627 shares of the Company's common stock,

par value $0.01 per share, at a purchase price of $3.72 per share, and (ii) to certain investors, in lieu of shares of common stock, 1,008,102 pre-funded warrants (the "Pre-Funded Warrants") at a price per Pre-Funded Warrant of $3.71 (the "Warrant Shares" and together with the Shares, the "Securities") with an exercise price of $0.01. As of June 30, 2024 the Pre-Funded Warrants have been exercised in full.

The Private Placement closed on March 19, 2024. We received gross proceeds of approximately $7.0 million, before deducting offering expenses payable by us.

Critical Accounting Estimates

There have been no material changes to the process of our critical accounting estimates as they were reported in our Annual Report on Form 10-K filed with the SEC on March 26, 2024.

Application of Critical Accounting Policies

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer (its Certifying Officers), evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of June 30, 2024, 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 U.S. Securities and Exchange Commission'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 six months ended June 30, 2024, 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 14 - "*Commitment and Contingencies - Litigation, Claims and Assessments - medac Matter*" for more information.

Item 1A. Risk Factors

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described in the Annual Report on Form 10-K filed on March 26, 2024. Our business faces significant risks and uncertainties, and those described in our Annual Report may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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.
10.1^	Amendment to the License, Supply and Contract Manufacturing Agreement, entered into on April 22, 2024 and effective as of May 1, 2024, by and between the Company and Synerx Pharma, LLC and Mylan Teoranta.
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 Principal Accounting 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 Principal Accounting 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.

^ Pursuant to Item 601(b)(10)(iv) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that the omitted information is (i) not material and (ii) the type of information that the registrant customarily and actually treats as private or confidential.

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.

August 5, 2024 /s/ Gerard Michel

Gerard Michel

Chief Executive Officer (Principal Executive Officer)

August 5, 2024 /s/ Sandra Pennell

Sandra Pennell

Principal Financial Officer

FIFTH AMENDMENT TO THE
LICENSE, SUPPLY AND CONTRACT MANUFACTURING AGREEMENT

This Fifth Amendment to the License, Supply, and Contract Manufacturing Agreement ("Fifth Amendment") is made and entered into as of May 1, 2024 ("Fifth Amendment Effective Date") between Synerx Pharma, LLC, a Pennsylvania limited liability company (“Synerx”) and Mylan Teoranta, a limited company formed under the laws of the Republic of Ireland (“Mylan Teoranta”) (Synerx and Mylan Teoranta are sometimes referred to collectively as “Mylan”); and Delcath Systems, Inc. (“Delcath”). Synerx, Mylan Teoranta and Delcath may be referred to herein individually as a "Party" and together as the "Parties".

Whereas, the Parties entered into that certain License, Supply and Contract Manufacturing Agreement dated October 13, 2010 ("Agreement");

Whereas, the Parties entered into the following amendments to the Agreement – First Amendment dated November 15, 2013; Second Amendment dated March 23, 2018; Restatement and Third Amendment dated June 22, 2021; and Fourth Amendment dated October 26, 2021 (the Agreement and all Amendments shall be hereinafter referred to collectively as the “Agreement”); and

Whereas, the Parties desire to further amend certain terms and conditions of the Agreement as set forth in this Fifth Amendment.

Now, therefore, intending to be legally bound and in consideration of the mutual promises, covenants and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the following:

1. Amendment to Section 3.4.

   Effective as of the Fifth Amendment Effective Date, the first sentence of Section 3.4(a) shall be deleted in its entirety and replaced with the following: “Delcath shall provide to Mylan, no later than the fifth business day of each calendar month, a rolling twenty-four (24) month forecast for its requirements of the Product (the ‘Rolling Forecast’).”

   Effective as of the Fifth Amendment Effective Date, the eighth sentence of Section 3.4(a) shall be deleted in its entirety and replaced with the following: “Such Purchase Orders shall provide a lead time of no less than two hundred and ten (210) days before the Delivery date.”

   Effective as of the Fifth Amendment Effective Date, the fourth sentence of Section 3.4(b) shall be deleted in its entirety and replaced with the following: “Upon receipt of an Incremental Purchase Order, Mylan shall use Commercially Reasonable Efforts to supply Product to Delcath at Delcath’s facility in Queensbury, NY, or such other facility within the United States as Delcath may indicate in such Incremental Purchase Order, on the Delivery date specified therein, provided that Incremental Purchase Orders must provide a lead time of no less than two hundred and ten (210) days before the Delivery date.”

2. Section 7.1 (Term) shall be replaced with the following:

   7.1 Term. The Agreement's term, unless otherwise earlier terminated in accordance herewith, shall be until December 31, 2028 ("Term"). The Term of this Agreement may be renewed for successive five-year periods upon mutual written consent of the Parties.

3. Amendment to Schedule A. Effective as of the Fifth Amendment Effective Date, Schedule A, including its addendum, shall be deleted in its entirety and replaced with Schedule A (Purchase Price) attached hereto and incorporated herein by reference.

4. The terms and provisions set forth in this Fifth Amendment shall modify and supersede all inconsistent terms and provisions set forth in the Agreement and except as specifically amended herein, all other terms and conditions of the Agreement remain in full force and effect. The Parties agree that the Agreement as amended by this Fifth Amendment shall continue to be legal, valid, binding and enforceable in accordance with its terms.

5. The captions and headings to this Fifth Amendment are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Fifth Amendment.

6. Counterparts and Electronic Transmission. This Fifth Amendment may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument. To the extent counterparts are signed and delivered by means of electronic transmission, they shall be treated in all manner and respects as an original contract and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person.

IN **WITNESS WHEREOF,** Mylan and Delcath have each caused this Fifth Amendment to be executed by their respective duly authorized representatives as of the Fifth Amendment Effective Date.

/s/ Martha Rook Date: April 22, 2024
Martha Rook
Chief Operating Officer
Delcath Systems, Inc.

/s/ Thomas D. Salus Date: April 22, 2024
Synerx Pharma LLC

By: Thomas D. Salus
Title: General Counsel – Corporate, Securities and Transactions

/s/ Arshad Majeed Date: April 22, 2024
Mylan Teoranta

By: Arshad Majeed
Title: Head of Global Injectables Operations

SCHEDULE A

Purchase Price

The Purchase Price of the Product, which shall be packaged in units each consisting of five vials, shall be [***]. The minimum order quantity, unless mutually agreed to by the Parties, is [***]. Standard lead time between placing a full batch purchase order and product delivery is approximately seven (7) months, with INCO terms of FOB destination. Full lots shall be received by Delcath with as near to thirty-six (36) months expiry dating as commercially practical.

Mylan may take an annual price increase of the Purchase Price of the Product equivalent to the percent increase of the [***] measured per calendar year. Mylan shall notify Delcath of any proposed revision to the Purchase Price in writing no later than thirty (30) days after the publication of the PPI for pharmaceutical preparation manufacturing. Delcath shall accept any such price increase consistent with the increase in PPI for pharmaceutical preparation manufacturing, but any other proposed modification of the Purchase Price of the Product must be mutually agreed in writing.

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.

August 5, 2024

/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.

August 5, 2024

/s/ Sandra Pennell
Sandra Pennell
Principal Financial 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 June 30, 2024, 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.

August 5, 2024

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

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 June 30, 2024, 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.

August 5, 2024

/s/ Sandra Pennell
Sandra Pennell
Principal Financial Officer