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, 2022

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.)**

1633 Broadway, Suite 22C
New York, NY 10019
(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 August 8, 2022, 8,597,682 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, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 10,203	$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	438	44
Inventories	2,040	1,412
Prepaid expenses and other current assets	2,370	2,743
Total current assets	19,202	31,152
Property, plant and equipment, net	1,457	1,348
Right-of-use assets	407	624
Total assets	$ 21,066	$ 33,124
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,067	$ 638
Accrued expenses	5,417	4,109
Deferred revenue	—	170
Lease liabilities	294	416
Loan payable, current	4,474	621
Total current liabilities	12,252	5,954
Lease liabilities, non-current	113	207
Loan payable, non-current	6,838	10,372
Convertible notes payable, non-current	4,709	4,639
Total liabilities	23,912	21,172
Commitments and contingencies	—	—
Stockholders' equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 7,906,728 shares issued and outstanding at June 30, 2022 and December 31, 2021	79	79
Additional paid-in capital	435,922	432,831
Accumulated deficit	(438,836)	(420,976)
Accumulated other comprehensive (loss) income	(11)	18
Total stockholders' equity (deficit)	(2,846)	11,952
Total liabilities and stockholders' equity	$ 21,066	$ 33,124

See accompanying Notes to 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,	
	2022	2021	2022	2021
Product revenue	$ 797	$ 398	$ 1,003	$ 659
Other revenue	—	138	171	265
Cost of goods sold	(180)	(202)	(214)	(314)
Gross profit	617	334	960	610
Operating expenses:				
Research and development expenses	5,456	3,497	9,696	7,204
Selling, general and administrative expenses	4,145	3,288	7,791	6,584
Total operating expenses	9,601	6,785	17,487	13,788
Operating loss	(8,984)	(6,451)	(16,527)	(13,178)
Interest expense, net	(665)	(40)	(1,309)	(81)
Other (loss) income	(8)	61	(24)	82
Net loss	(9,657)	(6,430)	(17,860)	(13,177)
Other comprehensive income:				
Foreign currency translation adjustments	(31)	(61)	(29)	33
Total other comprehensive loss	$ (9,688)	$ (6,491)	$ (17,889)	$ (13,144)
Common share data:				
Basic and diluted loss per common share	$ (1.18)	$ (0.96)	$ (2.18)	$ (2.00)
Weighted average number of basic and diluted shares outstanding	8,190,483	6,681,369	8,190,483	6,589,655

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2022	11,357	$ —	7,906,728	$ 79	$432,831	$ (420,976)	$ 18	$11,952
Compensation expense for issuance of stock options	—	—	—	—	1,474	—	—	1,474
Net loss	—	—	—	—	—	(8,203)	—	(8,203)
Total comprehensive income	—	—	—	—	—	—	2	2
Balance at March 31, 2022	11,357	—	7,906,728	79	434,305	(429,179)	20	5,225
Compensation expense for issuance of stock options	—	—	—	—	1,617	—	—	1,617
Net loss	—	—	—	—	—	(9,657)	—	(9,657)
Total comprehensive loss	—	—	—	—	—	—	(31)	(31)
Balance at June 30, 2022	11,357	$ —	7,906,728	$ 79	$435,922	$ (438,836)	$ (11)	$ (2,846)

	Preferred Stock $0.01 Par Value		Common Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)	Total
Balance at January 1, 2021	20,631	$ —	5,996,101	$ 60	$417,449	$ (395,327)	$ (104)	$22,078
Compensation expense for issuance of stock options	—	—	—	—	2,148	—	—	2,148
Shares settled for services	—	—	2,636	—	57	—	—	57
Conversion of Preferred stock into common stock	(150)	—	15,000	—	—	—	—	—
Exercise of warrants into common stock	—	—	237,520	3	2,373	—	—	2,376
Net loss	—	—	—	—	—	(6,747)	—	(6,747)
Total comprehensive income	—	—	—	—	—	—	94	94
Balance at March 31, 2021	20,481	—	6,251,257	63	422,027	(402,074)	(10)	20,006
Compensation expense for issuance of stock options	—	—	—	—	1,626	—	—	1,626
Conversion of Preferred stock into common stock	(8,774)		877,379	9	(8)	—	—	1
Exercise of warrants into common stock			221,141	2	15	—	—	17
Net loss			—	—	—	(6,430)	—	(6,430)
Total comprehensive loss			—	—	—	—	(61)	(61)
Balance at June 30, 2021	11,707	$ —	7,349,777	$ 74	$423,660	$ (408,504)	$ (71)	$15,159

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Six months ended June 30, 2022	2021
Cash flows from operating activities:		
Net loss	$ (17,860)	$ (13,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	3,091	3,774
Depreciation expense	31	78
Non-cash lease expense	234	—
Amortization of debt discount	380	—
Interest expense accrued related to convertible notes	80	79
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	374	485
Increase in accounts receivable	(394)	(17)
Increase in inventories	(628)	(366)
Increase (decrease) in accounts payable and accrued expenses	2,667	(2,036)
Decrease in lease liabilities	(217)	(155)
Decrease in deferred revenue	(170)	(334)
Net cash used in operating activities	(12,412)	(11,669)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(141)	(88)
Net cash used in investing activities	(141)	(88)
Cash flows from financing activities:		
Net proceeds from the exercise of warrants	—	2,393
Net cash provided by financing activities	—	2,393
Foreign currency effects on cash	(46)	33
Net decrease in total cash	(12,599)	(9,331)
Total Cash:		
Beginning of period	26,953	28,756
End of period	$ 14,354	$ 19,425
Cash, Cash Equivalents and Restricted Cash consisted of the following:		
Cash	$ 10,203	$ 19,274
Restricted Cash	4,151	151
Total	$ 14,354	$ 19,425

	Six months ended June 30, 2022	2021
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 842	$ 4
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Conversions of preferred stock into common stock	$ —	$ 9
Issuance of restricted stock for accrued fees due to a former board member	$ —	$ 57

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Notes to the Condensed Consolidated Financial Statements

(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, 2022 and 2021 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, 2021 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 30, 2022 and may also be found on the Company's website (www.delcath.com). In these notes to the interim condensed consolidated financial statements the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

The Company is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The Company's lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. HEPZATO has not been approved for sale in the United States. 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 of the liver.

The Company's clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM. The Company is currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications which will maximize the value of the HEPZATO platform.

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

In December 2021, the Company announced that the FOCUS Trial of HEPZATO met its pre-specified endpoint. Based on the FOCUS Trial results, the Company is preparing to submit a new drug application, or NDA, to the FDA for HEPZATO. The Company held a pre-NDA meeting with the FDA in April 2022. Based on the feedback from the FDA, the Company does not believe any additional pre-clinical or clinical studies are required to re-file the NDA. Due to vendor delays in delivering certain reports, the Company plans to submit an NDA to the FDA by the end of the third quarter of 2022. The Company has opened two Expanded Access Program sites to provide access to patients who meet the inclusion criteria during the pendency of FDA's review of HEPZATO.

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

Risks and Uncertainties

Although the Company is not aware of any direct impacts of the war between the Ukraine and the Russian Federation on its supply chain, the war could adversely impact the Company's ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its third-party suppliers in a timely manner or at all. In addition, at this time, although the Company is not aware of any direct impacts, the increase in COVID cases and associated restrictions, which could adversely impact the Company's ability to obtain components and/or significantly increase the cost of obtaining such components for the Company's products from its third-party suppliers in a timely manner or at all. The rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company's ability to meet anticipated timelines.

Liquidity and Going Concern

The accompanying interim condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses and has an accumulated deficit of $438.8 million as of June 30, 2022. These losses, among other factors, raise substantial doubt about the Company's ability to continue as a going concern.

On July 20, 2022, Delcath closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase Common Stock (the "Pre-Funded Warrants") to certain investors. Each share of Common Stock was sold at a price per share of $3.98 and the Pre-Funded Warrants were sold at a price of $3.97 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. Delcath received gross proceeds from the Private Placement of approximately $5.0 million before deducting offering expenses payable by Delcath. Delcath intends to use the net proceeds from the Private Placement for working capital purposes and other general corporate purposes.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or any commercialization efforts. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. If the Company is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment. The accompanying interim condensed consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. Additional working capital will be required to continue operations. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development and clinical trial results; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing, or sales experience; and dependence on key personnel.

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, 2022 and 2021; however, certain information and footnote disclosures normally included in our audited consolidated financial statements included in our Annual Report on Form 10-K 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, 2021.

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity." ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. ASU 2020-06 requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance in Accounting Standards Codification 260, Earnings per Share, relating to the computation of earnings per share for convertible instruments and contracts in an entity's own equity. The guidance becomes effective for the Company on January 1, 2024, with early adoption permitted. The Company early adopted ASU 2020-06 on January 1, 2022 and the adoption did not have any immediate effect on the Company's condensed consolidated financial statements. Going forward, the Company will no longer be required to assess convertible instruments for beneficial conversion features.

In October 2020, the FASB issued ASU 2020-10 “Codification Improvements”, which improves consistency by amending the Codification to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the Codification by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. The guidance was effective for the Company beginning in the first quarter of fiscal year 2022 with early adoption permitted. The Company adopted this guidance on January 1, 2022 and it did not have a material impact on its condensed consolidated financial statements.

On May 3, 2021, the FASB issued ASU 2021-04, “Earnings Per Share” (Topic 260), “Debt—Modifications and Extinguishments” (Subtopic 470-50), “Compensation—Stock Compensation” (Topic 718), and “Derivatives and Hedging—Contracts in Entity’s Own Equity” (Subtopic 815-40): “Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.” This new standard provides clarification and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company adopted this guidance on January 1, 2022 and it did not have a material impact on its condensed consolidated financial statements.

(2) Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded in *Restricted Cash* on the balance sheets. Restricted cash does not include required minimum balances.

Cash, cash equivalents, and restricted cash balances were as follows (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$10,203	$ 22,802
Restricted balance for loan agreement	4,000	4,000
Letters of credit	101	101
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash	$14,354	$ 26,953

Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, the Company is required to maintain a letter of credit which will expire with the sublease in February 2023.

(3) Inventories

Inventories consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 909	$ 767
Work-in-process	1,050	645
Finished goods	81	—
Total inventories	$2,040	$ 1,412

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Clinical trial expenses	$1,630	$ 1,630
Insurance premiums	400	890
Professional services	154	15
Other	186	208
Total prepaid expenses and other current assets	$2,370	$ 2,743

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following (in thousands):

	June 30, 2022	December 31, 2021	Estimated Useful Life
Buildings and land	$ 1,271	$ 1,222	30 years -Buildings
Enterprise hardware and software	1,853	1,858	3 years
Leaseholds	1,765	1,796	Lesser of lease term or estimated useful life
Equipment	1,221	1,094	7 years
Furniture	201	203	5 years
Property, plant and equipment, gross	6,311	6,173	
Accumulated depreciation	(4,854)	(4,825)	
Property, plant and equipment, net	$ 1,457	$ 1,348	

Depreciation expense for the six months ended June 30, 2022 was approximately $65,000 as compared to approximately $78,000 for the same period in 2021.

(6) Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Clinical expenses	$1,500	$ 1,517
Compensation, excluding taxes	1,228	893
Short-term financing	79	551
Professional fees	1,977	603
Interest on convertible note	473	393
Other	160	152
Total accrued expenses	$5,417	$ 4,109

(7) 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 and financing 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.

The following table summarizes the Company's operating leases as of and for the six months ended June 30, 2022 (in thousands):

	U.S.	Ireland	Total
Lease cost			
Operating lease cost	$ 203	$ 31	$ 234
Other information			
Operating cash flows out from operating leases	(203)	(31)	(234)
Weighted average remaining lease term	0.7	4.1	
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
Six Months Remaining December 31, 2022	$203	$ 20	$223
Year ended December 31, 2023	67	42	109
Year ended December 31, 2024	—	42	42
Year ended December 31, 2025	—	42	42
Year ended December 31, 2026	—	23	23
Total	270	169	438
Less present value discount	(8)	(24)	(32)
Operating lease liabilities included in the condensed consolidated balance sheets at June 30, 2022	$262	$ 145	$407

(8) Loans and Convertible Notes Payable

(in thousands)	June 30, 2022			December 31, 2021		
	Gross	Discount	Net	Gross	Discount	Net
Loan - Avenue [1]	12,638	(1,326)	11,312	12,638	(1,645)	10,993
Loan - Avenue [1] - Less Current Portion	(4,998)	524	(4,474)	(714)	93	(621)
Total - Loans Payable, Non-Current	$ 7,640	$ (802)	$ 6,838	$11,924	$(1,552)	$10,372
Convertible Note Payable - Rosalind	2,000	—	2,000	2,000	—	2,000
Convertible Portion of Loan Payable - Avenue	3,000	(291)	2,709	3,000	(361)	2,639
Total - Convertible Notes Payable - Non-Current	$ 5,000	$ (291)	$ 4,709	$ 5,000	$ (361)	$ 4,639

[1] The gross amount includes the 4.25% final payment of $638,000.

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

	Loans	Convertible Notes	Total
Year ended December 31, 2022	$ 714	$ —	$ 714
Year ended December 31, 2023	8,571	—	8,571
Year ended December 31, 2024	3,353	5,000	8,353
Total	$12,638	$ 5,000	$17,638

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 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, 2022 was 11.7% and increased to 12.45% for July 2022 and 13.2% effective August 2022. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024.

The initial tranche of the Avenue Loan is $15.0 million, including $4.0 million which has been funded into a restricted account and will be released upon achievement of (a)(x) positive FOCUS trial efficacy per the trial's predefined Statistical Analysis Plan (SAP) (specifically the Overall Response Rate exceeds the pre-specified threshold for success defined in the SAP by a statistically significant amount); and (y) based on data contained within the FOCUS trial database and appropriate for use with the U.S. Food and Drug Administration, safety and tolerability among FOCUS trial participants is within the range of currently approved and commonly used cytotoxic chemotherapeutic agents; and (b) raising subsequent net equity proceeds of at least $20 million. The Company may request an additional $5.0 million of gross proceeds between October 1, 2022 and December 31, 2022, with funding, subject to the approval of Avenue's Investment Committee.

Up to $3 million of the principal amount of the Avenue Loan outstanding may be converted, at the option of Avenue, into shares of the Company's common stock at a conversion price of $11.98 per share.

In connection with the Avenue Loan, the Company issued to Avenue a warrant (the "Avenue Warrant") to purchase 127,755 shares of common stock at an exercise price per share equal to $0.01. The Avenue Warrant is exercisable until August 31, 2026.

The Company will make monthly interest-only payments during the first fifteen months of the term of the Avenue Loan, which could be increased to up to twenty-four months upon the achievement of specified performance milestones. Following the interest-only period, the Company will make equal monthly payments of principal plus interest until the maturity date, when all remaining principal outstanding and accrued interest must be paid. If the Company prepays the Avenue Loan, it will be required to pay (a) a prepayment fee of 3% if the Avenue Loan is prepaid during the interest-only period; and (b) a prepayment fee of 1% if the Avenue Loan is prepaid after the interest-only period. The Company must make an incremental final payment equal to 4.25% of the aggregate funding.

The Company paid an aggregate commitment fee of $150,000 at closing. Upon funding a second tranche of the Avenue Loan, the Lender will earn a 1.0% fee on the $5.0 million of incremental committed capital, for a total commitment fee of $0.2 million.

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 judgments.

The Company determined that the embedded conversion option associated with the Avenue Loan was not required to be bifurcated. The Company determined that the Avenue Warrant met the criteria to be equity-classified. The $0.6 million value of the final payment was treated as original issue discount. The $1.2 million relative fair value of the Avenue Warrant was credited to Additional Paid in Capital while it was debited as debt discount. Of the $563,000 of cash issuance costs, $519,000 was allocated to the Avenue Loan and was recorded as debit discount, while $44,000 was allocated to the Avenue Warrant and was debited to Additional Paid in Capital. Of the $2.3 million of aggregate debt discount, $1.9 million was allocated to the non-convertible portion of the Avenue Loan, while $418,000 was allocated to the convertible portion of the Avenue Loan. Aggregate debt discount amortization of $0.5 million was recorded during the six months ended June 30, 2022, including $0.4 million related to the non-convertible portion of the Avenue Loan and $70,000 related to the convertible portion of the Avenue Loan. The Company also determined that the convertible portion of the Avenue Loan did not include a beneficial conversion feature, because the effective conversion price exceeded the commitment date market price of the Company's common stock. Interest expense incurred was $0.8 million for the six months ended June 30, 2022.

The Avenue Warrant was valued at issuance at $1.3 million using the Black-Scholes option pricing method using the following assumptions:

	August 6, 2021
Contractual term (years)	5.07
Expected volatility	187.0%
Risk-free interest rate	0.77%
Expected dividends	0.00%

Convertible Notes Payable

The Company has $2.0 million of principal outstanding related to Senior Secured Promissory Notes (the "Rosalind Notes") which bear interest at 8% per annum. Pursuant to their original terms, the Rosalind Notes were convertible into Series E Preferred Stock at a price of $1,500 per share and were to mature on July 16, 2021**.** Interest expense was $80,000 for the six months ended June 30, 2022 and 2021, respectively.

On August 6, 2021, the Company executed an agreement to amend the Rosalind Notes to (a) reduce the conversion price to $1,198 per share of the Company's Series E Convertible Preferred Stock; and (b) extend the maturity date to October 30, 2024.

In addition, in order to induce Avenue to provide the Avenue Loan described above, the holders of the Rosalind Notes agreed to subordinate (a) all of the Company's indebtedness and obligations to the holders; and (b) all of the holders' security interest, to the Avenue Loan and Avenue's security interest in the Company's property.

(9) Stockholders' Equity (Deficit)

Authorized Shares

The Company is authorized to issue 40,000,000 shares of common stock, $0.01 par value, and 10,000,000 shares of preferred stock, $0.01 par value. To date, the Company has designated the following preferred stock: Series A (4,200 shares), Series B (2,360 shares), Series C (590 shares), Series D (10,000 shares), Series E (40,000 shares) and Series E-1 (12,960 shares).

Preferred Stock

As of June 30, 2022, there were an aggregate of 11,357 shares of Series E and Series E-1 Convertible Preferred Stock outstanding.

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, 2022, there are 2,475,000 shares of common stock reserved under the 2020 Plan, of which 737,417 remained available to be issued.

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 (ESPP). The Company ESPP's plan provides for a maximum of 260,295 shares of common stock to be purchased by participating employees. Employees who elect to participate in the Company's 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.

Equity Offerings and Placements

At-the-Market Offering

On August 18, 2020, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, as sales agent or principal, shares of the Company's common stock, (the "Placement Shares"), having an aggregate offering price of up to $10.0 million (the "ATM Offering"). The Company has no obligation to sell any Placement Shares under the sales agreement. Subject to the terms and conditions of the sales agreement, Cantor Fitzgerald is required to use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Stock Market, to sell Placement Shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of Placement Shares, reimburse Cantor Fitzgerald's legal fees and disbursements up to $50,000 and provide Cantor Fitzgerald with customary indemnification and contribution rights. The sales agreement may be terminated by Cantor Fitzgerald or the Company upon notice to the other party as provided in the sales agreement, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares.

In connection with the ATM Offering, in consideration for a fee equal to 1.05% of the gross sales price per share sold in the ATM Offering, ROTH Capital Advisors, LLC ("Roth") waived, solely with respect to the ATM Offering, (i) Roth's right, pursuant to certain engagement letters dated August 14, 2019 and January 13, 2020 between Roth and the Company, to act as placement agent or underwriter with respect to offerings of the Company's securities and to receive a minimum of 35% of the fees paid to the agents or underwriters for such offerings and (ii) the lock-up provision included in a certain underwriting agreement dated May 1, 2020 between Roth and the Company requiring the prior written consent of Roth for any offer or sale of the Company's common stock by the Company during the 90-day period following the date of such underwriting agreement.

There were no shares sold during the six months ended June 30, 2022.

Private Placement

On July 20, 2022, Delcath closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase Common Stock (the "Pre-Funded Warrants") to certain investors. Each share of Common Stock was sold at a price per share of $3.98 and the Pre-Funded Warrants were sold at a price of $3.97 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. Delcath received gross proceeds from the Private Placement of approximately $5.0 million before deducting offering expenses payable by Delcath. Delcath intends to use the net proceeds from the Private Placement for working capital purposes and other general corporate purposes.

Stock Options

The Company values stock options using the Black-Scholes option pricing model and used the following assumptions during the reporting periods:

	Six months ended June 30,	
	2022	2021
Expected terms (years)	5.23 - 6.46	5.86
Expected volatility	174.81% -180.33%	178.33
Risk-free interest rate	1.75% -2.93%	0.9%
Expected dividends	0.00%	0.00%

The weighted average estimated fair value of the stock options granted during the six months ended June 30, 2022 and 2021 was approximately $6.31 and $9.87 per share, respectively.

The following is a summary of stock option activity for the six months ended June 30, 2022:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	1,732,460	$ 11.69		
Granted	650,083	7.05		
Expired	(29,116)	10.73		
Cancelled/Forfeited	(42,034)	10.35		
Outstanding at June 30, 2022	2,311,393	$ 10.42	8.7	$ —
Exercisable at June, 2022	952,670	$ 11.48	8.4	$ —

The following table summarizes information for stock option shares outstanding and exercisable at June 30, 2022:

		Options Exercisable	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
$6.24 - $53.85	2,310,894	8.7	952,171
$53.85+	499	6.6	499
	2,311,393	8.4	952,670

The following is a summary of share-based compensation expense in the statement of operations for the three and six months ended June 30, 2022 and 2021 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Selling, general and administrative	$ 918	$ 1,124	$ 1,958	$ 2,590
Research and development	503	463	1,025	1,093
Cost of goods sold	52	39	108	91
Total	$ 1,473	$ 1,626	$ 3,091	$ 3,774

At June 30, 2022, there was $8.0 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 2 years.

Warrants

The following is a summary of warrant activity for the six months ended June 30, 2022:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)
Outstanding at January 1, 2022	3,894,498	$ 9.27	
Warrants issued	—	—	
Warrants exercised	—	—	
Warrants expired	—	—	
Outstanding at June 30, 2022	3,894,498	$ 9.27	2.7
Exercisable at June 30, 2022	3,894,498	$ 9.27	2.7

The following table presents information related to stock warrants at June 30, 2022

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$0.01	283,755	3.4	283,755
$10.00	3,610,743	2.7	3,610,743
	3,894,498	2.7	3,894,498

(10) Net Loss per Common 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 and 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, 2022 and 2021 because their effects would be anti-dilutive:

	June 30,	
	2022	2021
Common stock warrants - equity	3,894,498	3,773,266
Assumed conversion of Series E and Series E-1 Preferred Stock	1,135,721	1,170,700
Assumed conversion of convertible notes	488,031	154,222
Stock options	2,315,643	1,091,888
Total	7,829,643	6,190,076

At June 30, 2022, the Company had 283,755 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three and six months ended June 30, 2022 and 2021:

	Six months ended June 30,		Three months ended June 30,	
	2022	2021	2022	2021
Weighted average shares issued	7,906,728	6,319,622	7,906,728	6,511,194
Weighted average pre-funded warrants	283,755	270,033	283,755	170,175
Weighted average shares outstanding	8,190,483	6,589,655	8,190,483	6,681,369

(11) Income Taxes

As discussed in Note 14 Income Taxes of the Company's Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations. Additional information regarding the statutes of limitations can be found in Note 14 Income Taxes of the Company's Annual Report.

(12) Commitments and Contingencies

Litigation, Claims and Assessments

medac Matter

In April 2021, the Company issued an invoice for €1 million (which currently converts to approximately $1.0 million) to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), the Company's EU product distribution partner, for a milestone payment due under the License, Supply and Marketing Agreement (the "License Agreement") dated December 10, 2018, between the Company and medac. Pursuant to the License Agreement, a milestone is due upon achieving positive efficacy in the FOCUS Trial as defined by the FOCUS Trial protocol. Per the trial protocol and associated Statistical Analysis Plan, positive efficacy is based on whether the Objective Response Rate (ORR) exceeds a pre-specified threshold. A preliminary analysis of the FOCUS Trial data based on 87% of enrolled patients was released on March 31, 2021, and subsequently presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held virtually from the 4th through the 8th of June 2021. Per that analysis, the ORR exceeded the pre-specified threshold. While the final ORR is not yet known, given the magnitude by which the ORR exceeded the pre-specified endpoint and the small number of patients yet to be assessed, the final ORR will be greater than the pre-specified endpoint regardless of the responder status of the remaining patients. medac disagrees that the milestone is due and claims that a full clinical study report is required in addition to the existing ORR analysis. medac has not disputed the accuracy of the ORR analysis or underlying data, but simply asserts that a full clinical study report is required prior to payment. While the Company disagrees with this interpretation, since medac has stated it does not intend to pay the invoice at this time, under revenue recognition criteria set out in ASC 606, the Company cannot recognize the revenue.

On October 12, 2021, the Company notified medac in writing that it was terminating the License Agreement due to medac's nonpayment of the milestone payment due under the License Agreement, with the effective date of termination of the License Agreement being April 12, 2022. medac disputed having an obligation to make a milestone payment under the Agreement and demanded withdrawal of the termination notice. The Company declined to withdraw the termination notice and, on December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution provisions of the License Agreement.

On December 30, 2021, the Company received a letter from medac stating that, due to its failure to withdraw the termination notice, medac was terminating the License Agreement with immediate effect. In the letter, medac reserved its rights in full, including a purported claim for damages for wrongful termination. In a separate letter, medac agreed to an orderly transition through February 28, 2022 in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately $0.2 million. The arbitration proceeding is moving forward with the parties agreeing to stay the arbitration for a finite period to pursue settlement discussions.

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, 2021 to provide an understanding of its results of operations, financial condition and cash flows.

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

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, and Section 27A of the Securities Act of 1933, as amended. 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 in Item 1A under "Risk Factors" and the risks detailed from time to time in our future reports filed with the Securities and Exchange Commission (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 and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and HEPZATO, generate revenue and successfully obtain reimbursement for the procedure and system;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of CHEMOSAT and HEPZATO and enter into supplier contracts;
- 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 and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. HEPZATO has not been approved for sale in the United States. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEZPATO, 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 of the liver.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or 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, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and neuroendocrine tumors) and one for doxorubicin in the treatment of patients with hepatocellular carcinoma).

Our most advanced development program is the treatment of ocular melanoma liver metastases, or mOM, a type of primary liver cancer. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of indications which will maximize the value of the HEPZATO platform. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint. Based on the FOCUS Trial results, the Company is preparing to submit a new drug application, or NDA, to the FDA for HEPZATO. The Company held a pre-NDA meeting with the FDA in April 2022. Based on the feedback from FDA, the Company does not believe any additional pre-clinical or clinical studies are required to re-file the NDA. Due to vendor delays in delivering certain reports, we plan to submit an NDA to the FDA by the end of the third quarter of 2022. The Company has opened two Expanded Access Program sites to provide access to patients who meet the inclusion criteria during the pendency of FDA's review of HEPZATO.

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

Results of Operations for the three and six months ended June 30, 2022 (in thousands)

Three months ended June 30, 2022 compared with three months ended June 30, 2021

Revenue

We recorded approximately $0.8 million in revenue for the three months ended June 30, 2022 compared to $0.4 million for the three months ended June 30, 2021. The increase in product revenue was primarily due to the transition to direct sales in Europe beginning in March 2022 which increased the average price per unit sold.

Cost of Goods Sold

For the three months ended June 30, 2022, cost of goods was relatively flat at $0.2 million for three months ended June 30, 2022 and 2021 as cost per unit sold were similar.

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. To date, these costs are related to generating pre-clinical data and the cost of manufacturing HEPZATO for clinical trials, conducting clinical trials and preparation costs for submission of HEPZATO to the FDA. For the three months ended June 30, 2022, research and development expenses increased to $5.5 million from $3.5 million in the prior year period. The increase of $2.0 million is primarily due to higher expenses in preparation of the pre-NDA meeting in April 2022 and preparation for the NDA submission by the third quarter of 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll, rent and professional services such as accounting and legal services. For the three months ended June 30, 2022 and 2021, selling, general and administrative expenses were $4.1 million and $3.3 million, respectively. The increase is primarily higher costs in the preparation for commercialization of HEPZATO in the United States early next year.

Other Income/Expense

Other income (expense) is primarily related to income or expense associated with financial instruments. For the three months ended June 30, 2022 and 2021, other expenses were $0.7 million and $40,000, respectively. The increase in other expenses is primarily due to the interest expense and amortization expense for the original issue discount on the debt financing transaction discussed below between the Company and its lender, Avenue Venture Opportunities Fund, L.P.

Six months ended June 30, 2022 compared with six months ended June 30, 2021

Revenue

We recorded approximately $1.2 million in revenue for the six months ended June 30, 2022 compared to $0.9 million for the six months ended June 30, 2021. The increase in product revenue was primarily due to the transition to direct sales in Europe beginning in March 2022 which increased the average price per unit sold.

Cost of Goods Sold

For the six months ended June 30, 2022, cost of goods slightly decreased $100,000 from $0.3 million for the six months ended June 30, 2021 to $0.2 million for six months ended June 30, 2022 primarily due to the revaluation of inventory for 2022.

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. To date, these costs are related to generating pre-clinical data and the cost of manufacturing HEPZATO for clinical trials, conducting clinical trials and preparation costs for submission of HEPZATO to the FDA. For the six months ended June 30, 2022, research and development expenses increased to $9.7 million from $7.2 million in the prior year period. The increase of $2.5 million is primarily due to higher expenses in preparation for the pre-NDA meeting in April 2022 and preparation for the NDA submission by the end of the third quarter of 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll, rent and professional services such as accounting and legal services. For the six months ended June 30, 2022 and 2021, selling, general and administrative expenses were $7.8 million and $6.6 million, respectively. The increase is primarily higher costs in the preparation for commercialization of HEPZATO in the United States early next year and slightly higher headcount and related costs.

Other Income/Expense

Other income (expense) is primarily related to income or expense associated with financial instruments. For the six months ended June 30, 2022, other income/expenses was a net expense of $1.3 million and other income/expenses was a de minimis amount for the six months ended June 30, 2021. The change in other income/expenses is primarily due to interest expense and amortization expense for the original issue discount on the debt financing transaction between the Company and its lender, Avenue Venture Opportunities Fund, L.P.

Liquidity and Capital Resources

At June 30, 2022, we had cash, cash equivalents and restricted cash totaling $14.4 million, During the six months ended June 30, 2022, the Company used $12.4 million of cash in our operating activities.

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 consistent profitability. We have historically funded our operations through a combination of private placements and public offerings of our securities. We will need to raise additional capital under structures available to us, including debt and/or equity offerings.

These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities to support our future operations.

Our capital commitments over the next twelve months include $7.8 million to satisfy June 30, 2022 accounts payable, accrued expenses and lease liabilities and $5.0 million of loan principal payments. Our capital commitments past the next twelve months include (a) $0.1 million of lease liabilities; (b) $7.6 million of loan principal payments; and (c) $5.0 million of convertible note principal payments, if the holders do not elect to convert the notes into equity.

We also expect to use cash, cash equivalents and investment proceeds to fund our clinical research and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining regulatory approvals and complying with applicable laws and regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

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, 2022 was 11.7% and increased to 12.45% for July 2022 and 13.2% effective August 2022. The Avenue Loan is secured by all of the Company's assets globally, including intellectual property. The Avenue Loan matures on August 1, 2024. Additional information regarding the Avenue Loan can be found in Note 8 to the Company's unaudited interim consolidated financial statements contained in this Quarterly Report on Form 10-Q.

On July 20, 2022, Delcath closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase Common Stock (the "Pre-Funded Warrants") to certain investors. Each share of Common Stock was sold at a price per share of $3.98 and the Pre-Funded Warrants were sold at a price of $3.97 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. Delcath received gross proceeds from the Private Placement of approximately $5.0 million before deducting offering expenses payable by Delcath. Delcath intends to use the net proceeds from the Private Placement for working capital purposes and other general corporate purposes.

Critical Accounting Estimates

During the six months ended June 30, 2022, there were no material changes to critical accounting estimates as reported in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 30, 2022 and may also be found on the Company's website (www.delcath.com).

Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America. During the six months ended June 30, 2022, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. A description of certain accounting policies that may have a significant impact on amounts reported in the financial statements is disclosed in Note 3 to the Company's Annual Report for the fiscal year ended December 31, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our principal executive and principal accounting officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act). Based on that evaluation, our principal executive and principal accounting officer concluded that our disclosure controls and procedures as of June 30, 2022 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our principal executive and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2022 that has materially affected, or is 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

In April 2021, the Company issued an invoice for €1 million (which currently converts to approximately $1.2 million) to medac GmbH, a privately held, multi-national pharmaceutical company based in Germany ("medac"), the Company's EU product distribution partner, for a milestone payment due under the License, Supply and Marketing Agreement (the "License Agreement") dated December 10, 2018, between the Company and medac. Pursuant to the License Agreement, a milestone is due upon achieving positive efficacy in the FOCUS Trial as defined by the FOCUS Trial protocol. Per the trial protocol and associated Statistical Analysis Plan, positive efficacy is based on whether the Objective Response Rate (ORR) exceeds a pre-specified threshold. A preliminary analysis of the FOCUS Trial data based on 87% of enrolled patients was released on March 31, 2021, and subsequently presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held virtually from the 4th through the 8th of June 2021. Per that analysis, the ORR exceeded the pre-specified threshold. While the final ORR is not yet known, given the magnitude by which the ORR exceeded the pre-specified endpoint and the small number of patients yet to be assessed, the final ORR will be greater than the pre-specified endpoint regardless of the responder status of the remaining patients. medac disagrees that the milestone is due and claims that a full clinical study report is required in addition to the existing ORR analysis. medac has not disputed the accuracy of the ORR analysis or underlying data, but simply asserts that a full clinical study report is required prior to payment. While the Company disagrees with this interpretation, since medac has stated they do not intend to pay the invoice at this time, under revenue recognition criteria set out in ASC 606, the Company did not recognize the revenue.

On October 12, 2021, the Company notified medac in writing that it was terminating the License Agreement due to medac's nonpayment of the milestone payment due under the License Agreement, with the effective date of termination of the License Agreement being April 12, 2022. medac disputed having an obligation to make a milestone payment under the Agreement and demanded withdrawal of the termination notice. The Company declined to withdraw the termination notice and, on December 16, 2021, the Company initiated an arbitration proceeding pursuant to the dispute resolution provisions of the License Agreement.

On December 30, 2021, the Company received a letter from medac stating that, due to its failure to withdraw the termination notice, medac was terminating the License Agreement with immediate effect. In the letter, medac reserved its rights in full, including a purported claim for damages for wrongful termination. In a separate letter, medac agreed to orderly transition through February 28, 2022 in order to minimize the impact of any termination on patients and physicians. The Company agreed to purchase inventory held at medac in March 2022 for approximately $0.2 million. The arbitration proceeding is moving forward with the parties agreeing to stay the arbitration for a finite period to pursue settlement discussions.

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	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2).
10.1	Form of Securities Purchase Agreement, dated July 18, 2022 by and among the Company and private parties thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 20, 2022).
10.2	Form of Registration Rights Agreement, dated July 18, 2022, by and among the Company and private parties thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 20, 2022).
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 Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any filing, except to the extent the Company specifically incorporates it by reference.

DELCATH SYSTEMS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DELCATH SYSTEMS, INC.

August 8, 2022 /s/ Gerard Michel

Gerard Michel
Chief Executive Officer (Principal Executive Officer)

August 8, 2022 /s/ Anthony Dias

Anthony Dias
Principal Accounting Officer

DELCATH SYSTEMS, INC.

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

I, Gerard Michel, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc.;

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

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

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

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

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

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

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

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

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

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

August 8, 2022

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

DELCATH SYSTEMS, INC.

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

I, Anthony Dias, 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 8, 2022

/s/ Anthony Dias
Anthony Dias
Principal Accounting Officer

Exhibit 32.1

DELCATH SYSTEMS, INC.

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

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended June 30, 2022, 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 8, 2022

/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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony Dias, 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 8, 2022

/s/ Anthony Dias
Anthony Dias
Principal Accounting Officer