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

FORM 10-Q

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

For the quarterly period ended March 31, 2021

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 May 11, 2021, 6,472,398 shares of the Company's common stock, $0.01 par value, were outstanding.

SYSTEMS, INC.

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

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 26,600	$ 28,575
Restricted cash	50	181
Accounts receivable, net	75	57
Inventories	1,109	855
Prepaid expenses and other current assets	2,369	2,670
Total current assets	30,203	32,338
Property, plant and equipment, net	1,321	1,351
Right-of-use assets	791	946
Total assets	$ 32,315	$ 34,635
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,234	$ 1,774
Accrued expenses	5,927	5,241
Deferred revenue, current	502	525
Lease liabilities, current	433	495
Convertible notes payable, current	2,000	2,000
Total current liabilities	10,096	10,035
Deferred revenue, non-current	1,856	2,072
Lease liabilities, non-current	357	450
Total liabilities	12,309	12,557
Commitments and contingencies (Note 13)	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 20,480 and 20,631 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 6,251,257 and 5,996,101 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	63	60
Additional paid-in capital	422,027	417,449
Accumulated deficit	(402,074)	(395,327)
Accumulated other comprehensive income	(10)	(104)
Total stockholders' equity	20,006	22,078
Total liabilities and stockholders' equity	$ 32,315	$ 34,635

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 March 31,	
	2021	**2020**
Product revenue	$ 261	$ 176
Other revenue	127	118
Cost of goods sold	(112)	(78)
Gross profit	276	216
Operating expenses:		
Research and development expenses	3,707	2,974
Selling, general and administrative expenses	3,296	2,316
Total operating expenses	7,003	5,290
Operating loss	(6,727)	(5,074)
Change in fair value of the warrant liability, net	—	(2,832)
Interest expense, net	(41)	(36)
Other income	21	81
Net loss	(6,747)	(7,861)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	94	65
Total other comprehensive loss	$ (6,653)	$ (7,796)
Common share data:		
Basic loss per common share	$ (1.04)	$ (108.07)
Diluted loss per common share	$ (1.04)	$ (108.07)
Weighted average number of basic shares outstanding	6,496,922	72,740
Weighted average number of diluted shares outstanding	6,496,922	72,740

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	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 loss	—	—	—	—	—	—	94	94
Balance at March 31, 2021	20,481	$ -	6,251,257	$ 63	$ 422,027	$ (402,074)	$ (10)	$ 20,006

	Preferred Stock $0.01 Par Value		Common Stock Issued $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at January 1, 2020	41,517	$ —	67,091	$ 1	$ 364,785	$ (371,171)	$ 28	$ (6,357)
Compensation expense for issuance of stock options	—	—	—	—	25	—	—	25
Shares settled for services	—	—	2,717	—	30	—	—	30
Conversion of Preferred stock into common stock	(70)	—	2,915	—	—	—	—	—
Fractional rounding related to Reverse Stock Split	—	—	50	—	—	—	—	—
Registration costs	—	—	—	—	(106)	—	—	(106)
Fair value of warrants reclassified from liability to equity	—	—	—	—	6,199	—	—	6,199
Net loss	—	—	—	—	—	(7,861)	—	(7,861)
Total comprehensive loss	—	—	—	—	—	—	65	65
Balance at March 31, 2020	41,447	$ —	72,773	$ 1	$ 370,933	$ (379,032)	$ 93	$ (8,005)

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three months ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (6,747)	$ (7,861)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	2,148	25
Restricted stock compensation expense	—	30
Depreciation expense	39	48
Amortization of right of use assets	—	11
Warrant liability fair value adjustment	—	2,832
Non-cash interest income	(1)	(3)
Interest expense accrued related to convertible notes	39	40
Changes in assets and liabilities:		
(Increase) decrease in prepaid expenses and other assets	302	(880)
Increase in accounts receivable	(18)	(48)
Increase in inventories	(254)	(136)
Increase in accounts payable and accrued expenses	164	901
Decrease in deferred revenue	(239)	(188)
Net cash used in operating activities	(4,567)	(5,229)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(9)	(180)
Net cash used in investing activities	(9)	(180)
Cash flows from financing activities:		
Principal payments on financing leases	—	(11)
Net payments related to registration costs	—	(106)
Net proceeds from the exercise of warrants	2,376	—
Net cash provided by/(used in) financing activities	2,376	(117)
Foreign currency effects on cash	94	64
Net decrease in total cash	(2,106)	(5,462)
Total Cash:		
Beginning of period	28,756	10,183
End of period	$ 26,650	$ 4,721

	Three months ended March 31,	
	2021	**2020**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 3	$ 4
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Reclassification of 2019 warrants from liability to equity	$ —	$ 6,199
Issuance of restricted stock for accrued fees due to a former board member	$ 57	$ —

See accompanying Notes to 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 months ended March 31, 2021 and 2020 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, 2020 (the "Annual Report"), which was filed with the Securities and Exchange Commission (the "SEC") on March 31, 2021 and may also be found on the Company's website (www.delcath.com). In these notes to the condensed consolidated financial statements the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

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. HEPZATO is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our commercial product is a stand-alone medical device having the same device components as the HEPZATO KIT but without the melphalan hydrochloride. The device 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.

Our clinical development program for HEPZATO is primarily comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (FOCUS Trial), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM. 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 follow-on indications which will maximize the value of the HEPZATO platform.

Risks and Uncertainties

Due to the global outbreak of SARS-CoV-2, a novel strain of coronavirus that causes Coronavirus disease (COVID-19), the Company experienced an impact on certain areas of its business. These effects included a slowing of patient recruitment in the FOCUS trial and a reduction in the pace at which we can monitor data at our clinical trial sites. The resulting delay in completing enrollment and additional time required to monitor data caused our announcement for the top-line data from our FOCUS Trial to shift to early 2021 and to be modified to a preliminary analysis. We now plan to submit a New Drug Application (NDA) to the FDA in the first quarter of 2022 for the treatment of mOM. The ability to achieve this goal is contingent on our ability to monitor data at our clinical sites and therefore the timeline may shift as access to the clinical sites changes in response to the rapidly evolving situation. We have also experienced an increased volatility in EU commercial product revenue and additional impacts to the business may arise that we are not aware of currently. The ultimate impact of the pandemic on the Company's results of operations, financial position, liquidity, or capital resources cannot be reasonably estimated at this time.

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 losses since inception and expects to continue incurring losses for the next several years. These losses, among other factors, raise substantial doubt about the Company's ability to continue as a going concern.

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 Delcath 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 entities controlled by Delcath and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim condensed consolidated financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and cash flows for the interim periods ended March 31, 2021 and 2020; 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, 2020, except for the following:

Reclassifications. Certain prior period balances have been reclassified in order to conform to current period presentation. These reclassifications have no effect on previously reported results of operations or loss per share.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, Simplifying the Accounting for Income Taxes. The list of changes is comprehensive; however the changes will not significantly impact the Company due to the full valuation allowance that is recorded against the Company's deferred tax assets. Early adoption of ASU 2019-12 is permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued. An entity that elects to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, an entity that elects early adoption must adopt all the amendments in the same period. The Company adopted ASU 2019-12 on January 1, 2021 and there was no material impact on the Company's financial statements or disclosures.

(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:

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 26,600	$ 28,575
Letters of credit	—	131
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 26,650	$ 28,756

(3) Inventories

Inventories consist of the following:

	March 31, 2021	December 31, 2020
Raw materials	$ 486	$ 435
Work-in-process	623	420
Total inventories	$ 1,109	$ 855

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2021	December 31, 2020
Clinical trial expenses	$ 1,497	$ 1,497
Insurance premiums	498	845
Professional services	125	66
Other	249	262
Total prepaid expenses and other current assets	$ 2,369	$ 2,670

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2021	December 31, 2020	Estimated Useful Life
Buildings and land	$ 1,120	$ 1,109	30 years - Buildings
Enterprise hardware and software	1,861	1,862	3 years
Leaseholds	1,809	1,826	Lesser of lease term or estimated useful life
Equipment	1,061	1,063	7 years
Furniture	203	204	5 years
Property, plant and equipment, gross	6,054	6,064	
Accumulated depreciation	(4,733)	(4,713)	
Property, plant and equipment, net	$ 1,321	$ 1,351	

On July 31, 2020, the Company exercised its option to purchase its 95-97 Park Road office location in Queensbury, NY for $460.3, pursuant to the terms of the lease agreement dated September 17, 2018, as amended on January 29, 2019, and further amended on July 31, 2020.

Depreciation expense for the three months ended March 31, 2021 was approximately $38.8 as compared to approximately $47.6 for the same period in 2020.

(6) Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2021	December 31, 2020
Clinical expenses	$ 3,511	$ 2,698
Compensation, excluding taxes	1,514	1,598
Professional fees	335	225
Interest on convertible note	274	234
Other	293	486
Total accrued expenses	$ 5,927	$ 5,241

(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 three months ended March 31, 2021:

	US	Ireland	Total
Lease cost			
Operating lease cost	$ 112	$ 57	$ 169
Sublease income	—	(44)	(44)
Total	$ 112	$ 13	$ 125
Other information			
Operating cash flows out from operating leases	(112)	(57)	(169)
Operating cash flows in from operating leases	-	44	44
Weighted average remaining lease term	1.9	0.3	
Weighted average discount rate - operating leases	8%	8%	

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

	US	Ireland	Total
Year ended December 31, 2021	$ 304	$ 73	$ 377
Year ended December 31, 2022	406	-	406
Year ended December 31, 2023	67	-	67
Total	777	73	850
Less present value discount	(59)	(1)	(60)
Operating lease liabilities included in the condensed consolidated balance sheet at March 31, 2021	$ 718	$ 72	$ 790

(8) Convertible notes payable

	Conversion price	Current interest rate	Principal
Current convertible notes payable			
8.0% July 2019 Notes (maturity date - July 16, 2021)	$ 1,500	8%	$ 2,000

The note payable is convertible into Preferred Stock.

(9) Stockholders' Equity

Preferred Stock

Series E and Series E-1 Preferred Stock

During the three months ended March 31, 2021, 150 shares of Preferred Stock were converted into 15,000 shares of the Company's common stock.

As of March 31, 2021, there were an aggregate of 20,481 shares of Series E and Series E-1 Preferred Stock outstanding.

Other Common Stock Issuances

During the three months ended March 31, 2021, the Company issued 237,520 shares of common stock associated with the exercise of warrants.

Issuance of Unregistered Securities

In February 2021, the Company issued 2,636 shares of unregistered common stock in lieu of a cash payment of deferred accrued director fees to a former director.

Stock Incentive Plans

2020 Omnibus Equity Incentive Plan

As of March 31, 2021, there were 675,000 shares of the Company's common stock reserved under the 2020 Plan, of which 95,000 remained available to be issued. On March 30, 2021, the Company's Board of Directors approved an amendment of the 2020 Plan to increase the number of shares of the Company's common stock available for issuance under the 2020 Plan by 1,800,000, subject to stockholder approval of the amendment. The amendment of the 2020 Plan was approved by the stockholders at the Company's annual meeting of stockholders held on May 6, 2021 and, effective as of such date, the number of shares of the Company's common stock available for issuance under the 2020 Plan increased by 1,800,000 resulting in a total share reserve of 2,475,000 shares of common stock.

Share-Based Compensation

The following is a summary of stock option activity under the 2019 Plan and the 2020 Plan for the three months ended March 31, 2021:

	Number of Option	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	1,078,499	$ 12.68		
Granted	—	—		
Exercised	—	—		
Cancelled/Forfeited	—	—		
Outstanding at March 31, 2021	1,078,499	$ 12.68	9.5	$ 710
Exercisable at March 31, 2021	175,164	$ 13.05	9.5	$ 131

The following table summarizes information for stock option shares outstanding and exercisable at March 31, 2021

		Options Exercisable	
Range of Exercise Prices	Outstanding Number of Options	Weighted Average Remaining Option Term (in years)	Number of Options
$10 - $15	946,000	9.5	157,665
$15 - $20	81,000	9.5	8,500
$20 - $25	51,000	9.5	8,500
$25+	499	7.8	499
	1,078,499	9.5	175,164

The following is a summary of share-based compensation expense in the statement of operations for the three months ended March 31, 2021

	Three months ended March 31,	
	2021	2020
Selling, general and administrative	$ 1,466	$ 49
Research and development	630	5
Cost of goods sold	52	—
Total	$ 2,148	$ 55

At March 31, 2021, there was $6,677 of aggregate unrecognized compensation expense related employee and board stock option grants. This will be recognized over the next 33 months.

Warrants

The following is a summary of warrant activity for the three months ended March 31, 2021:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	4,236,687	$ 9.13		
Warrants issued	—	—		
Warrants exercised	(242,580)	10.00		
Warrants expired	—	—		
Outstanding at March 31, 2021	3,994,107	$ 9.07	3.9	$ 13,372
Exercisable at March 31, 2021	3,994,107	$ 9.07	3.9	$ 13,372

The following table presents information related to stock warrants at March 31, 2021

		Warrants Exercisable	
Range of Exercise Prices	Outstanding Number of Warrants	Weighted Average Remaining Warrant Term (in years)	Number of Warrants
$ 0.01	371,000	4.1	371,000
$ 10.00	3,623,107	3.9	3,623,107
	3,994,107	3.9	3,994,107

As of March 31, 2021, warrants to purchase 371,000 shares of the Company’s common stock were pre-funded, and the exercise price was $0.01 per share. The remaining warrants were exercisable at $10.00 per share.

(10) Fair Value Measurements

As a result of the expiration of certain provisions in the 2019 Warrants, the $6,199 fair value of the 2019 Warrants was reclassified from liability to equity on February 19, 2020.

The fair value of the outstanding warrants at February 19, 2020, the date the 2019 Warrants were no longer classified as a liability, was determined by using option pricing models with the following assumptions:

	February 19, 2020
Expected life (in years)	4.3
Expected volatility	208.2%
Risk-free interest rates	1.4%

(11) 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 March 31, 2021 and 2020 because their effects would be anti-dilutive:

	March 31,	
	2021	2020
Stock options	1,078,499	1,640
Common stock warrants - equity	3,994,107	1,826,599
Common stock reserved for conversion of preferred shares	2,048,101	1,799,093
Assumed conversion of convertible notes	146,288	63,493
Total	7,266,995	3,690,825

At March 31, 2021, the Company had 371,000 pre-funded warrants outstanding. The following table provides a reconciliation of the weighted average shares outstanding calculation for the three months ended March 31, 2021 and 2020:

	Three months ended March 31,	
	2021	2020
Weighted average shares issued	6,125,922	72,740
Weighted average pre-funded warrants	371,000	-
Weighted average shares outstanding	6,496,922	72,740

(12) Commitments and Contingencies

Litigation, Claims and Assessments

Following the May 18, 2020 resignation (effective June 1, 2020) of Jennifer Simpson, the Company's former President and Chief Executive Officer, and Barbra Keck, the Company's former Chief Financial Officer (the "Claimants"), it became evident that there was a dispute regarding the Company's compensation obligations to the Claimants. In a letter dated June 29, 2020, an attorney representing the Claimants made certain claims and threatened litigation against the Company. On or about July 27, 2020, the Claimants filed a statement of claim with the American Arbitration Association against the Company. The Claimants seek payment of certain purported unpaid compensation amounts claimed to be due to them, in an approximate amount of $1,140 in the aggregate, as well as unspecified statutory damages under New York Labor Law, attorneys' fees and costs, and statutory interest. The Company intends to defend the claims vigorously. The arbitrator had scheduled hearings to take place during the week of May 17, 2021. However, the Claimants and the Company recently agreed to participate in non-binding mediation of their dispute before a neutral mediator, which resulted in the arbitration proceedings being placed in abeyance pending the outcome of the mediation process. At this time, the mediation process between the Claimants and the Company is ongoing. As of March 31, 2021, the Company has accrued for the full purported unpaid compensation amounts.

(13) Subsequent Events

Stock Warrant Exercises

Subsequent to March 31, 2021, warrants to purchase 6,141 shares of the Company's common stock with an exercise price of $10.00 per share were exercised for proceeds of $61.4. In addition, pre-funded warrants to purchase 215,000 shares of the Company's common stock with an exercise price of $0.01 per share were exercised for proceeds of $2.2.

Other Transactions

In April 2021, the Company issued an invoice for $1,178 to medac, the Company's EU product distribution partner, for the achievement of the milestone requirement pertaining to the positive results related to the FOCUS trial, as outlined in the License, Supply and Marketing Agreement dated December 10, 2018 between the Company and medac.

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, 2020 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, 2020 in Item 1A under "Risk Factors" and in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," 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 Delcath Hepatic Delivery system;
- the progress and results of our research and development programs;
- our expectations about the COVID-19 pandemic and any potential disruption or impact to our operations;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of CHEMOSTAT 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.

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Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q as well as Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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. HEPZATO is 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, our commercial product is a stand-alone medical device having the same device components as the HEPZATO KIT but without the melphalan hydrochloride. The device 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 regulated as a combination drug and device by the United States 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 active moiety melphalan hydrochloride five orphan drug designations for the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and neuroendocrine tumors. The FDA has granted the active moiety doxorubicin one orphan drug designation for the treatment of patients with hepatocellular carcinoma. In Europe, CHEMOSAT is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing CHEMOSAT in select markets in the United Kingdom and the European Union, or the EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Our most advanced development program is the treatment of ocular melanoma liver metastases, or mOM, a type of primary liver cancer, with HEPZATO. HEPZATO is being studied in the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (FOCUS Trial), a global registration clinical trial that is investigating objective response rate in mOM. The FOCUS Trial is being conducted at approximately 30 sites in the United States and Europe. The FOCUS Trial initiated treatment on the final enrolled patient on October 2, 2020. The primary endpoint of the FOCUS Trial is Objective Response Rate (ORR) as measured by RECISTv1.1, in the Intent to Treat (ITT) population. The single arm trial was powered to demonstrate a superior ORR versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications. The checkpoint inhibitor ORR was calculated based on a meta-analysis covering 16 different publications which included 476 patients. The pooled overall response rate was 5.5% [95% CI: 3.6, 8.3]. To achieve statistical significance at a 95% Confidence Interval the lower bound of the ORR for HEPZATO is required to exceed the 8.3% upper bound of the meta-analysis. Secondary endpoints include Duration of Response (DOR), Disease Control Rate (DCR), Overall Survival (OS), and Progression-Free Survival (PFS). Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety, and other pharmacokinetic measures. Initially, the trial was a randomized controlled trial which was amended to a single arm trial given slow enrollment due to the rarity of ocular melanoma, absence of crossover to the experimental trial arm, competing clinical trials and the commercial availability of CHEMOSAT in Europe. Included in the prespecified analyses are comparisons against the Best Alternative Care (BAC) arm which enrolled 32 patients prior to the amendment to a single-arm trial.

We have paused a global Phase 3 clinical trial of HEPZATO in patients with intrahepatic cholangiocarcinoma, (the ALIGN Trial) due to difficulties in enrollment. In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and support of select investigator-initiated trials, or IITs.

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. This may result in a restart of the ALIGN Trial. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

Recent Developments

FOCUS Trial Preliminary Analysis

On March 31, 2021 Delcath released a preliminary analysis of the FOCUS trial data based on 87% of enrolled patients using prespecified analyses. An Independent Review Committee assessed an ORR of 29.2% [95% CI: 20.1, 39.8] in the ITT population, the lower bound of which exceeded the upper bound of the predefined success criteria (8.3%) for the primary ORR endpoint. In the per protocol populations, evaluable patients in the HEPZATO arm had a statistically significant improvement over BAC in prespecified endpoints including: ORR of 32.9% [95% CI: 22.8, 44.4] versus 13.8% [CI: 3.9, 31.7] for the BAC arm (Chi-square $P<0.05$), Median PFS of 9.0 months [95% CI: 6.2, 11.8] versus 3.1 months ([95% CI: 2.7, 5.7] for the BAC arm (HR=0.41 $p<0.001$), and DCR of 70.9% [95% CI: 59.6, 80.6] versus 37.9% [95% CI: 20.7, 57.7] for the BAC arm ($p<0.002$). In this preliminary analysis, DOR and OS

were not yet evaluable. Since not all patients were evaluable for all time points, these preliminary analyses may change as data matures.

In the HEPZATO safety population of 94 patients, 38 patients (40.4%) experienced a treatment-emergent serious adverse event. The most commonly reported treatment-emergent serious adverse events were thrombocytopenia (14.9% of patients), neutropenia (10.6% of patients), and leukopenia (4.2% of patients), which were well-manageable. 5% of patients experienced treatment-emergent serious cardiac adverse events. In all cases the events resolved with no ongoing complications. There were no treatment-related deaths in the trial.

COVID-19

Due to the global outbreak of SARS-CoV-2, a novel strain of coronavirus that causes Coronavirus disease (COVID-19), the Company experienced an impact on certain areas of its business. These effects included a slowing of patient recruitment in the FOCUS Trial and a reduction in the pace at which we can monitor data at our clinical trial sites. The resulting delay in completing enrollment and additional time required to monitor data caused our announcement for the top-line data from our FOCUS Trial to shift to early 2021 and to be modified to a preliminary analysis. We intend to submit a New Drug Application (NDA) to the FDA in the first quarter of 2022 for the treatment of mOM once the FOCUS Trial has been completed. The ability to achieve this goal is contingent on our ability to monitor data at our clinical sites and therefore the timeline may shift as access to the clinical sites changes in response to the rapidly evolving situation. COVID-19 has caused us to experience an increase in volatility in EU commercial product revenue. The results of the FOCUS Trial should also support securing reimbursement coverage for the use of CHEMOSAT in Europe. Additional impacts of COVID-19 on our business may arise that we are not aware of currently. The ultimate impact of the pandemic on the Company's results of operations, financial position, liquidity, or capital resources cannot be reasonably estimated at this time.

Medical Device Directive Transition to Medical Device Regulation

The European Commission recently reviewed the Medical Device Directive legislative framework and promulgated REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. This new Medical Device Regulation became effective on May 25, 2017, marking the start of a 3-year transition period for manufacturers selling medical devices in Europe to comply with the new medical device regulation, or MDR, which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution, and post marketing evaluation. As a result of the worldwide COVID-19 pandemic, on April 17, 2020, the European Parliament adopted the European Commission's proposal to postpone the implementation of the MDR (EU) 2017/745 by 12 months. This urgently drafted proposal to delay the MDR is in response to the exceptional circumstances associated with the COVID-19 pandemic and the potential impact it may have had on the MDR implementation. The new Date of Application (DoA) for the MDR will be May 26, 2021.

Effectively addressing these changes will require a complete review of our device operations to determine what is necessary to comply. We do not believe the MDR regulatory changes will impact our business at this time, though implementation of the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

Results of Operations for the three months ended March 31, 2021 (in thousands)

Three months ended March 31, 2021 Compared with Three months ended March 31, 2020

Revenue

We recorded approximately $388.5 in revenue for the three months ended March 31, 2021 compared to $293.4 for the three months ended March 31, 2020. The increase in revenue is partly due to an increase in CHEMOSAT unit sales to medac and an increase of 5% for the royalty income calculation from medac, which started on January 1, 2021.

Cost of Goods Sold

For the three months ended March 31, 2021, we recorded cost of goods sold of approximately $111.9 compared to $78.0 for the three months ended March 31, 2020. An increase of $38.8 is related to the increase in sales volume.

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 and conducting clinical trials. For the three months ended March 31, 2021, research and

development expenses increased to $3,707.4 from $2,974.0 in the prior year period. The increase is primarily due to the recording stock option expenses of $630 in the first quarter of 2021.

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 March 31, 2021 and 2020, selling, general and administrative expenses were $3,296.0 and $2,315.5, respectively. The increase is primarily related to the recording of stock option expense of $1,466 during the three months ended March 31, 2021.

Other Income/Expense

Other income/expense is primarily related to income or expense associated with financial instruments. For the three months ended March 31, 2021 and 2020, other income/expense were $20.2 and $2,786.4 of expense, respectively. The prior year period included a $2,831 expense related to the change in fair value of a warrant liability.

Net Loss

Our net loss for the three months ended March 31, 2021 was $6,746.9, a decrease of $1,114.0 compared to net loss of $7,860.5 for the three months ended March 31, 2020. The decrease in net loss is primarily due to the $2,831 other income/expense related to the change in the fair value of the warrant liability booked in the three months ended March 31, 2020 which was offset by the recording of $2,148 stock option expense in the first quarter of 2021.

Liquidity and Capital Resources

At March 31, 2021, we had cash, cash equivalents and restricted cash totaling $26,650.0, as compared to cash, cash equivalents and restricted cash totaling $28,756.0 at December 31, 2020 and $4,721.0 at March 31, 2020. During the three months ended March 31, 2021 and 2020, we used $4,566.7 and $5,229.3, respectively, of cash in our operating activities. In the three months ended March 31, 2021, we raised $2,376 of cash related to the exercises of warrants.

These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the financial statements included elsewhere in this Quarterly Report on Form 10-Q 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 future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history, and we anticipate that our losses will continue for the foreseeable future. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our future clinical 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 approvals and complying with 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.

The Company has no off-balance sheet arrangements.

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 three months ended March 31, 2021, 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, 2020. 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 audited consolidated financial statements contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Item 3.Quantitative and Qualitative Disclosures about Market Risk

We may be minimally exposed to market risk through changes in market interest rates that could affect the interest earned on our cash balances.

We measure all derivatives, including certain derivatives embedded in contracts, at fair value and recognize them on the balance sheet as an asset or a liability, depending on our rights and obligations under the applicable derivative contract.

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our Chief Executive Officer and Interim 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 Chief Executive Officer and Interim Principal Accounting Officer concluded that our disclosure controls and procedures as of March 31, 2021 (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 Chief Executive Officer and Interim 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 define in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended March 31, 2021 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.

Following the May 18, 2020 resignation (effective June 1, 2020) of Jennifer Simpson, the Company's former President and CEO, and Barbra Keck, the Company's former CFO (the "Claimants"), it became evident that there was a dispute regarding the Company's compensation obligations. In a letter dated June 29, 2020, an attorney representing the Claimants made certain claims and threatened litigation against the Company. On or about July 27, 2020, the Claimants filed a statement of claim with the American Arbitration Association against the Company. The Claimants seek payment of certain purported unpaid compensation amounts claimed to be due to them, in an approximate amount of $1.14 million in the aggregate, as well as unspecified statutory damages under New York Labor Law, attorneys' fees and costs, and statutory interest. The Company intends to defend the claims vigorously. The arbitrator had scheduled hearings to take place during the week of May 17, 2021. However, the Claimants and the Company recently agreed to participate in non-binding mediation of their dispute before a neutral mediator, which resulted in the arbitration proceedings being placed in abeyance pending the outcome of the mediation process. At this time, the mediation process between the Claimants and the Company is ongoing. As of March 31, 2021, the Company has accrued for the full purported unpaid compensation amounts.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods.

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

On February 18, 2021, the Company issued 2,636 shares of unregistered common stock in lieu of cash payment of deferred accrued director fees to former director, William Rueckert. The issuance to Mr. Rueckert was made in reliance on the exemption from registration in Section 4(a)(2) under the Securities Act of 1933.

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).
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 Interim 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 Interim 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 *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *

* 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.

May 11, 2021

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer

May 11, 2021

/s/ Christine Padula
Christine Padula
Interim Principal Accounting Officer

Exhibit 31.1

DELCATH SYSTEMS, INC.

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

I, Gerard Michel, certify that:

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

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

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

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

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

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

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

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

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

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

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

May 11, 2021

/s/ Gerard Michel
Gerard Michel
Chief 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, Christine Padula, certify that:

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

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

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

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

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

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

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

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

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

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

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

May 11, 2021

/s/ Christine Padula
Christine Padula
Interim 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 March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerard Michel, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

May 11, 2021

/s/ Gerard Michel
Gerard Michel
Chief 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 March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christine Padula, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

May 11, 2021

/s/ Christine Padula
Christine Padula
Interim Principal Accounting Officer