

**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, 2020

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-16133

**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

**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	DCTH	The Nasdaq Capital Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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 14, 2020, 2,760,401 shares of the Company's common stock, \$0.01 par value, were outstanding.

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

	March 31, 2020	December 31, 2019
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,540	\$ 10,002
Restricted cash	181	181
Accounts receivables, net	69	21
Inventories	790	654
Prepaid expenses and other current assets	2,642	1,759
<b>Total current assets</b>	<b>8,222</b>	<b>12,617</b>
Property, plant and equipment, net	867	735
Right-of-use assets	688	860
<b>Total assets</b>	<b>\$ 9,777</b>	<b>\$ 14,212</b>
<b>Liabilities and Stockholders' Deficit</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 4,997	\$ 4,533
Accrued expenses	7,424	6,947
Lease liabilities, current portion	622	664
Warrant liability	—	3,368
<b>Total current liabilities</b>	<b>13,043</b>	<b>15,512</b>
Deferred revenue	2,672	2,860
Lease liabilities, long-term portion	67	197
Convertible notes payable, long-term	2,000	2,000
<b>Total liabilities</b>	<b>17,782</b>	<b>20,569</b>
Commitments and contingencies	—	—
<b>Stockholders' deficit</b>		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; 41,447 and 41,517 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$.01 par value; 1,000,000,000 shares authorized; 72,773 and 67,091 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively*	1	1
Additional paid-in capital	370,933	364,785
Accumulated deficit	(379,032)	(371,171)
Accumulated other comprehensive income	93	28
<b>Total stockholders' deficit</b>	<b>(8,005)</b>	<b>(6,357)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 9,777</b>	<b>\$ 14,212</b>

\* reflects, a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

*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,	
	2020	2019
Product revenue	\$ 176	\$ 90
Other revenue	118	180
Cost of goods sold	(78)	(96)
Gross profit	216	174
Operating expenses:		
Research and development expenses	2,974	3,298
Selling, general and administrative expenses	2,316	2,549
Total operating expenses	5,290	5,847
Operating loss	(5,074)	(5,673)
Change in fair value of the warrant liability, net	(2,832)	7
Interest expense	(56)	(2,229)
Other income	101	2
Net loss	<u>\$ (7,861)</u>	<u>\$ (7,893)</u>
Other comprehensive (loss) income:		
Foreign currency translation adjustments	65	57
Total other comprehensive loss	<u>\$ (7,796)</u>	<u>\$ (7,836)</u>
Common share data:		
Basic loss per common share*	<u>\$ (108.07)</u>	<u>\$ (75.11)</u>
Diluted loss per common share*	<u>\$ (108.07)</u>	<u>\$ (75.11)</u>
Weighted average number of basic shares outstanding*	72,740	105,084
Weighted average number of diluted shares outstanding*	72,740	105,084

\* reflects, one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

*See accompanying Notes to Condensed Consolidated Financial Statements.*

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

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

  

	Common Stock Issued \$0.01 Par Value		Preferred Stock \$0.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	No. of Shares	Amount	No. of Shares	Amount				
Balance at January 1, 2019	14,715	\$ —	101	\$ —	\$ 329,065	\$ (344,054)	\$ 50	\$ (14,939)
Compensation expense for issuance of stock options	—	—	—	—	54	—	—	54
Compensation expense for issuance of restricted stock	20	—	—	—	4	—	—	4
Issuance of Series D Preferred Stock	—	—	15	—	150	—	—	150
Conversion of Series D Preferred Stock to Debt	—	—	(116)	—	(1,160)	—	—	(1,160)
Exercise of pre-funded warrants	5,885	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(7,893)	—	(7,893)
Total comprehensive income	—	—	—	—	—	—	7	7
Balance at March 31, 2019	20,620	\$ —	—	\$ —	\$ 328,113	\$ (351,947)	\$ 57	\$ (23,777)

\*reflects a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

*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,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,861)	\$ (7,893)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	25	54
Restricted stock compensation expense	30	4
Depreciation expense	48	65
Amortization of right of use assets	172	—
Warrant liability fair value adjustment	2,832	(7)
Non-cash interest income	(3)	—
Interest expense accrued related to convertible notes	40	51
Debt discount amortization	—	2,160
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	(880)	(108)
Decrease in accounts receivable	(48)	523
Decrease in inventories	(136)	61
Decrease in accounts payable and accrued expenses	901	2,902
Deferred revenue	(188)	(120)
Principal payments on operating leases	(161)	—
Decrease in other non-current liabilities	—	(462)
Net cash used in operating activities	<u>(5,229)</u>	<u>(2,770)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(180)	(2)
Net cash (used in) investing activities	<u>(180)</u>	<u>(2)</u>
<b>Cash flows from financing activities:</b>		
Principal payments on financing leases	(11)	—
Net proceeds from the issuance of debt	—	400
Net proceeds from sale of Series D Preferred Stock	—	150
Registration of Series E and Series E-1 Preferred stock and related warrants	(106)	—
Net cash (used in) provided by financing activities	<u>(117)</u>	<u>550</u>
Foreign currency effects on cash	64	(30)
Net (decrease) increase in cash and cash equivalents	<u>(5,462)</u>	<u>(2,252)</u>
<b>Cash and cash equivalents:</b>		
Beginning of period	10,183	3,578
End of period	<u>\$ 4,721</u>	<u>\$ 1,326</u>

*See accompanying Notes to Condensed Consolidated Financial Statements.*

**DEL CATH 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 months ended March 31, 2020 and 2019 should be read in conjunction with the consolidated financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the “Annual Report”), which was filed with the Securities Exchange Commission (the “SEC”) on March 25, 2020 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***

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (“Melphalan/HDS”) —is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our system is commercially available under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (“CHEMOSAT”), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our clinical development program (“CDP”) for Melphalan/HDS 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 mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the “ALIGN Trial”). Our CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials (“IITs”).

The recent outbreak of a novel strain of coronavirus (COVID-19) has had an impact on our ability to monitor data at our clinical trial sites and is likely to cause a decline in product revenue for the foreseeable future as many hospitals are prioritizing the treatment of patients diagnosed with COVID-19. This situation is rapidly changing 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***

The accompanying 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. We anticipate incurring losses until such time, if ever, that it can generate significant sales. As discussed in Note 13, in May 2020 we consummated an underwritten public offering resulting in gross proceeds of approximately \$22.0 million. We expect that the proceeds of the offering and our existing cash resources will be sufficient to fund our expected operations through the second quarter of 2021. We may need to raise additional capital in the future to support our operations. We expect that any such financing activity will involve the public or private offering of our equity and/or equity-related securities. If we are unable to obtain sufficient capital to fund our operations, we would be required to curtail certain aspects of our operations or consider other means of obtaining additional financing, although there is no guarantee that we would be able to obtain the financing necessary to continue its operations.

***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, 2020 and 2019; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company’s results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

### Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 *Summary of Significant Accounting Policies* to the Consolidated Financial Statements included in the Company's Annual Report filed for the fiscal year ended December 31, 2019.

### Recently Issued 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 will adopt ASU 2019-12 in 2021.

### (2) 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:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 4,540	\$ 10,002
Letters of credit	131	131
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	<u>\$ 4,721</u>	<u>\$ 10,183</u>

### (3) Inventories

Inventories consist of the following:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Raw materials	\$ 448	\$ 375
Work-in-process	342	279
Total inventories	<u>\$ 790</u>	<u>\$ 654</u>

### (4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

<i>(in thousands)</i>	March 31, 2020	December 31, 2019
Clinical trial expenses	\$ 1,497	\$ 725
Insurance premiums	423	589
Professional Service Fees	518	—
Other <sup>1</sup>	204	445
Total prepaid expenses and other current assets	<u>\$ 2,642</u>	<u>\$ 1,759</u>

<sup>1</sup> Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at March 31, 2020 and December 31, 2019.



(5) **Property, Plant, and Equipment**

Property, plant, and equipment consist of the following:

<i>(in thousands)</i>	<b>March 31, 2020</b>	<b>December 31, 2019</b>	<b>Estimated Useful Life</b>
Buildings and land	\$ 634	\$ 589	30 years - Buildings
Enterprise hardware and software	1,763	1,739	3 years
Leaseholds	1,787	1,695	Lesser of lease term or estimated useful life
Equipment	1,032	1,025	7 years
Furniture	202	198	5 years
Property, plant and equipment, gross	5,418	5,246	
Accumulated depreciation	(4,551)	(4,511)	
Property, plant and equipment, net	<u>\$ 867</u>	<u>\$ 735</u>	

Depreciation expense for the three months ended March 31, 2020 was approximately \$0.1 million as compared to approximately \$0.1 million for the same period in 2019.

(6) **Accrued Expenses**

Accrued expenses consist of the following:

<i>(in thousands)</i>	<b>March 31, 2020</b>	<b>December 31, 2019</b>
Clinical Expenses	\$ 2,580	\$ 2,497
Compensation, excluding taxes	3,933	3,525
Professional fees	361	263
Other <sup>1</sup>	550	662
Total accrued expenses	<u>\$ 7,424</u>	<u>\$ 6,947</u>

<sup>1</sup> Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at March 31, 2020 and December 31, 2019.

(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 and financing leases as of and for the three months ended March 31, 2020:

<i>(in thousands)</i>	<u>US</u>	<u>Ireland</u>	<u>Total</u>
<b>Lease Cost</b>			
Operating lease cost	\$ 118	\$ 52	\$ 170
Financing lease cost	12	—	12
Sublease income	—	(43 )	(43 )
<b>Total</b>	<u>\$ 130</u>	<u>\$ 9</u>	<u>\$ 139</u>
<b>Other information</b>			
Operating cash flows out from operating leases	(118 )	(52 )	(170 )
Operating cash flows in from operating leases	-	43	43
Operating cash flows out from financing leases	(11 )	—	(11 )
Right-of-use assets exchanged for new operating lease liabilities	—	—	—
Weighted average remaining lease term	0.9	1.3	
Weighted average discount rate - operating leases	8 %	8 %	

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

<i>(in thousands)</i>	<u>US</u>	<u>Ireland</u>	<u>Total</u>
Year ended December 31, 2020	\$ 369	\$ 154	\$ 523
Year ended December 31, 2021	78	120	198
<b>Total</b>	<u>447</u>	<u>274</u>	<u>721</u>
Less present value discount	(17)	(15)	(32)
Operating lease liabilities included in the condensed consolidated balance sheet at March 31, 2020	<u>\$ 430</u>	<u>\$ 259</u>	<u>\$ 689</u>

## (8) Outstanding Debt

On June 6, 2019, the Company entered into an agreement with two institutional investors, pursuant to which the investors agreed to transfer and surrender to the Company for cancellation of warrants to purchase 5,605 shares of the Company's common stock (the "Series D Warrants") and warrants to purchase 0.1 million shares of the Company's common stock (the "Pre-Funded Series D Warrants"). Under the terms of the Purchase Agreement, the Company agreed to sell and issue to the investors 8% Senior Secured Promissory Notes in an aggregate principal amount of \$2.0 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants. This agreement was effective on July 15, 2019, upon the closing of the Company's Private Placement discussed further in Notes 10 and 11 to the Company's audited consolidated financial statements contained in its Annual Report for the fiscal year ended December 31, 2019. Following the closing of the Private Placement, the Company entered into an agreement under which the 8% Senior Secured Promissory Notes became convertible into shares of Series E Preferred Stock and Warrants (the "Unit") at the price of \$1,500 per Unit. The principal is recognized in Convertible notes payable, long-term on the Condensed Consolidated Balance Sheet.

The following tables provide a summary of the various notes outstanding at March 31, 2020:

	<u>Conversion price</u>	<u>Current interest rate</u>	<u>Principal</u>
<b>Long term convertible notes payable</b>			
8.0% July 2019 Notes	\$ 1,500	8%	\$ 2,000,000

## (9) Stockholders' Equity

### **Preferred Stock**

#### *Series E and Series E-1 Preferred Stock*

On July 11, 2019, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which Delcath sold to investors an aggregate of 20,000 shares of our Series E convertible preferred stock, par value \$0.01 per share, or the Series E Preferred Stock, at a price of \$1,000 per share and a warrant, or a 2019 E Warrant, to purchase a number of shares of common stock equal to the number of shares of common stock issuable upon conversion of the Series E Preferred Stock purchased by the investor, or the July 2019 Private Placement. In connection with the July 2019 Private Placement, the Company exchanged \$11.8 million of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and

related 2019 Warrants, \$0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related 2019 Warrants and issued 923 shares of Series E Preferred Stock and related 2019 Warrants to certain investors in exchange for a waiver of rights under exchange agreements signed in December 2018 and March 2019, or the Debt Exchange.

On August 19, 2019, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which Delcath sold to investors an aggregate of 9,510 shares of Series E-1 convertible preferred stock, par value \$0.01 per share, or the Series E-1 Preferred Stock, at a price of \$1,000 per share and a warrant, or a 2019 E-1 Warrant, and together with the 2019 E Warrant, the 2019 Warrants, to purchase a number of shares of common stock of the Company equal to the number of shares of common stock issuable upon conversion of the Series E-1 Preferred Stock purchased by the investor, or the August 2019 Private Placement, and, collectively with the July 2019 Private Placement, the Private Placements.

Each share of Series E Preferred Stock and Series E-1 Preferred Stock, or, collectively, the Preferred Stock, is convertible at any time at the option of the holder into the number of shares of common stock determined by dividing the current conversion price. At March 31, 2020, the conversion price was \$23.04 and was subsequently adjusted to \$10.00 upon the pricing of a \$22.0 million offering on May 1, 2020 and discussed further in Note 13. The holders of the Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an “as converted” basis) to and in the same form as dividends paid on shares of the common stock. Any such dividends that are not paid to the holders of the Preferred Stock will increase the stated value. No other dividends will be paid on shares of Preferred Stock.

Each 2019 Warrant had an exercise price equal to \$23.04 at March 31, 2020. The exercise price was subsequently adjusted to \$10.00 upon the pricing of a \$22.0 million offering on May 1, 2020 and discussed further in Note 13. The 2019 Warrants are exercisable until 5:00 p.m. (NYC time) on December 24, 2024.

As of March 31, 2020, there were 41,447 shares of Preferred Stock outstanding and 1.8 million 2019 Warrants outstanding.

### **Common Stock Issuances**

During the three months ended March 31, 2020 the Company issued 2,915 shares of the Company’s common stock pursuant to conversions of Series E and Series E-1 Preferred Stock.

### **Share-Based Compensation**

The Company’s 2019 Equity Incentive Plan (the “Plan”) allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company’s officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares reserved for issuance under the Plan is 2,142. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant. As of March 31, 2020, the Plan had approximately 502 shares available for grant.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	1,640	\$ 196.70	9.1	\$ —
Granted	—			
Exercised	—			
Cancelled/Forfeited	—			
Outstanding at March 31, 2020	1,640	\$ 196.70	8.9	\$ —
Exercisable at March 31, 2020	1,640	\$ 196.70	8.9	\$ —

At March 31, 2020, there was no unrecognized compensation expense related to non-vested share-based compensation awards under the plans for employee and board stock option grants. For the three months ended March 31, 2020, the Company recognized share-based compensation expense of approximately \$54,000 in the statement of operations, which includes 2,717

shares of restricted common stock issued as compensation for certain advisory services. For the same period in 2019, the Company recognized share-based compensation expense of approximately \$54,000 in the statement of operations.

<i>(in thousands)</i>	Three months ended March 31,			
	2020		2019	
Selling, general and administrative	\$	49	\$	43
Research and development		5		11
Total	\$	54	\$	54

### Warrants

The following is a summary of warrant activity for the three months ended March 31, 2020:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2019	1,826,608	\$7.00 - \$23.04	\$ 23.04	5.0
Issued	—			
Exercised	—			
Expired	(9)			
Outstanding at March 31, 2020	1,826,599	\$7.00 - \$23.04	\$ 23.04	4.7

### (10) Fair Value Measurements

As a result of the expiration of certain provisions in the 2019 Warrants they were reclassified from liability to equity on February 19, 2020.

The table below presents the activity within Level 3 of the fair value hierarchy for the three months ended March 31, 2020:

#### Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

<i>(in thousands)</i>	Warrant Liability
Balance at December 31, 2019	\$ 3,368
Total change in the liability included in earnings	2,832
Fair value of warrants reclassified from liability to equity	(6,200)
Balance at March 31, 2020	\$ —

The fair value of the outstanding warrants at February 19, 2020, the date the 2019 Warrants were no longer classified as a liability, and December 31, 2019 was determined by using option pricing models with the following assumptions:

	February 19, 2020	December 31, 2019
Expected life (in years)	4.3	4.6
Expected volatility	208.2%	207.5%
Risk-free interest rates	1.4%	1.7%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2020, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

<i>(in thousands)</i>	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Total	
	March 31, 2020	December 31, 2019	March 31, 2020	December 31, 2019	March 31, 2020	December 31, 2019	March 31, 2020	December 31, 2019
Liabilities								
Derivative instrument liabilities	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 3,368	\$ —	\$ 3,368

For the periods ended March 31, 2020 and December 31, 2019, there were no transfers in or out of Level 1, 2 or 3 inputs.

#### (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. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

The following potentially dilutive securities were excluded from the computation of earnings per share as of March 31, 2020 and 2019 because their effects would be anti-dilutive:

	March 31,	
	2020	2019
Stock options	1,640	1,166,667
Common stock warrants - equity	1,826,599	4,202,909
Common stock warrants - liabilities	—	189,029
Common stock reserved for conversion of preferred shares	1,799,093	—
Assumed conversion of convertible notes	63,493	268,558
Total	<u>3,690,825</u>	<u>5,827,163</u>

#### (12) 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.

On March 27, 2020, President Trump signed into law the \$2 trillion bipartisan Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748). The CARES Act includes a variety of economic and tax relief measures intended to stimulate the economy, including loans for small businesses, payroll tax credits/deferrals, and corporate income tax relief. Due to the Company's history of tax loss carryforwards and full valuation allowance, the CARES Act did not have a significant effect to the income tax provision, as the corporate income tax relief was directed towards cash taxpayers.

#### (13) Subsequent Events

##### *Public Offering and Nasdaq Uplisting*

On May 5, 2020, the Company closed a public offering of 2.2 million shares of common stock (or common stock equivalents) and Series F warrants to purchase up to 2.2 million shares of common stock. Delcath received gross proceeds of approximately \$22.0 million from the offering, before deducting the underwriting discount and estimated offering expenses. The securities

were offered pursuant to a registration statement on Form S-1 (File No. 333-235904) previously filed with the SEC and declared effective on April 30, 2020. In connection with this offering, the Company's common stock was approved for listing and began trading on the Nasdaq Capital Market on May 1, 2020. As a result of this offering, the Series E and Series E-1 Preferred Stock conversion price was adjusted to \$10.00 and the exercise price of the 2019 Warrants was adjusted to \$10.00.

***Preferred Stock Conversions***

From April 1, 2020 through May 14, 2020, the Company issued 0.8 million shares of Common Stock upon the conversion of Series E and Series E-1 Preferred Stock.

## 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 as of included in the Company’s Annual Report for the fiscal year ended December 31, 2019 to provide an understanding of its results of operations, financial condition and cash flows.

### 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 this Quarterly Report on Form 10-Q in Part II, Item 1A under “Risk Factors” as well as in Part I, Item 3 “Quantitative and Qualitative Disclosures About Market Risk,” our Annual Report for the fiscal year ended December 31, 2019 in Item 1A under “Risk Factors” as well as in Item 7A “Quantitative and Qualitative Disclosures About Market Risk,” and the risks detailed from time to time in our future SEC reports. 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 Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and 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 the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and Melphalan/HDS;
- 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.

### 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 for the fiscal year ended December 31, 2019.

### Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe,

Melphalan/HDS is approved for sale under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial.

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial.

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 sponsorship of select investigator-initiated trials, or IITs.

In the United States, Melphalan/HDS 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. The FDA has granted us six orphan drug designations, including three orphan designations for the potential use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

### **Recent Developments**

We expected to announce top-line data from our FOCUS trial in mid-2020. However, the COVID-19 pandemic has impacted our ability to enroll and treat patients in this trial and to monitor data at our clinical trial sites. As a result, we will not be able to release the top-line data from the FOCUS Trial within the timeframe we had anticipated. Once our clinical trial sites are able to return to normal operating procedures, we will assess the impact and update our expected timing accordingly.

On May 5, 2020, we closed a public offering of 2.2 million shares of common stock (or common stock equivalents) and Series F warrants to purchase up to 2.2 million shares of common stock. We received gross proceeds of approximately \$22.0 million from the offering, before deducting the underwriting discount and estimated offering expenses. The securities were offered pursuant to a registration statement on Form S-1 (File No. 333-235904) previously filed with the SEC and declared effective on April 30, 2020. In connection with this offering, the Company's common stock was approved for listing and began trading on the Nasdaq Capital Market on May 1, 2020.



## **Results of Operations for the three months ended March 31, 2020; Comparisons of Results of Operations for three months ended March 31, 2019**

### **Revenue**

We had product sales revenue of approximately \$0.2 million for the three months ended March 31, 2020 compared to \$0.1 million for the three months ended March 31, 2019. The increase is resulted from an increase in royalties received pursuant to our licensing agreement with medac.

### **Cost of Goods Sold**

For the three months ended March 31, 2020, we recorded cost of goods sold of approximately \$0.1 million compared to \$0.1 million for the three months ended March 31, 2019. The decrease of approximately \$20,000 resulted primarily from an adjustment to our standard cost calculation.

### **Research and Development Expenses**

Research and development expenses are incurred for the development of Melphalan/HDS 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 Melphalan/HDS for clinical trials and conducting clinical trials. For the three months ended March 31, 2020 and 2019, research and development expenses decreased to \$3.0 million from \$3.3 million. The decrease was primarily due lower active enrollment in our FOCUS trial which was fully enrolled during the first quarter of 2020.

### **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, 2020 and 2019, selling, general and administrative expenses were \$2.3 million and \$2.5 million, respectively. The decrease is primarily related to reduced personnel expenses as a result of reduced headcount.

### **Change in the fair value of the warrant liability**

For the three months ended March 31, 2020 the change in the fair value of the warrant liability was approximately \$2.8 million as compared to approximately \$7,000 for the three months ended March 31, 2019. The increase of \$2.8 million resulted from an increased number of outstanding warrants being recognized as liabilities during the three months ended March 31, 2020. As a result of the expiration of certain provisions in the 2019 Warrants, the 2019 Warrants have been reclassified as equity on our March 31, 2020 balance sheet. The warrant liability is discussed in more detail in Note 10 to the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

### **Other Income/Expense**

Other expense and interest expense are primarily related to the amortization of debt discounts in the 2020 and 2019 periods. For the three months ended March 31, 2020, other expense and interest expense resulted primarily from interest accrued on our long-term convertible note discussed in Note 8 of the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, as well as foreign currency exchange gains and losses. Other income and interest expenses also consists of interest income from a money market account and interest earned on operating accounts.

Other income and interest expense also consists of interest income from a money market account and interest earned on operating accounts.

### **Net Loss**

Our net loss for the three months ended March 31, 2020 was \$7.9 million, a decrease of \$32,000, compared to net loss of \$7.9 million for the three months ended March 31, 2019. The slight decrease in net loss is primarily due to a \$0.6 million decrease in operating expenses, which was offset by a \$0.6 million increase in non-cash expense items including the fair value of the warrant liability and interest expense.

## Liquidity and Capital Resources

As discussed in Note 13, in May 2020 we consummated an underwritten public offering resulting in gross proceeds of approximately \$22.0 million. We expect that the proceeds of the offering and our existing cash resources will be sufficient to fund our expected operations through the second quarter of 2021. We may need to raise additional capital in the future to support our operations. We expect that any such financing activity will involve the public or private offering of our equity and/or equity-related securities. If we are unable to obtain sufficient capital to fund our operations, we would be required to curtail certain aspects of our operations or consider other means of obtaining additional financing, although there is no guarantee that we would be able to obtain the financing necessary to continue its operations.

At March 31, 2020, we had cash, cash equivalents and restricted cash totaling \$4.7 million, as compared to cash, cash equivalents and restricted cash totaling \$10.2 million at December 31, 2019 and \$1.3 million at March 31, 2019. During the three months ended March 31, 2020 and 2019, we used \$5.2 million and \$2.8 million respectively, of cash in its operating activities.

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.

### Application of Critical Accounting Policies

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). During the three months ended March 31, 2020, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2019. 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, 2019.

### 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 its cash balances.

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

The proceeds allocated to the warrants we issued in 2019 (the "2019 Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period and were reclassified to equity during the first quarter of 2020. For the three months ended March 31, 2020, we recorded pre-tax derivative instrument loss of \$2.8 million. As a result of the reclassification from liability to equity, there was no derivative liability on the balance sheets at March 31, 2020. Management expects that the warrants outstanding at March 31, 2020 will either be exercised or expire worthless. The fair value of the 2019 Warrants at February 19, 2020, the date the 2019 Warrants were no longer classified as a liability, was determined by using option pricing models assuming the following:

	February 19, 2020	December 31, 2019
Expected life (in years)	4.3	4.6
Expected volatility	208.2%	207.5%
Risk-free interest rates	1.4%	1.7%

#### **Item 4. Controls and Procedures**

##### *Evaluation of Disclosure Controls and Procedures*

Management, with the participation of our Chief Executive Officer, evaluated the effectiveness of the design and operation of its 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 Chief Financial Officer concluded that our disclosure controls and procedures as of March 31, 2020 (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 Chief Financial 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, 2020 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.

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 1A. Risk Factors

There have been no material changes from the risk factors disclosed in “Part I, Item 1A—Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2019.

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

On February 26, 2020, we issued 2,717 shares of restricted common stock in relation to certain advisory services received by us. In connection with the foregoing, we relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

### Item 3. Defaults upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not Applicable.

### Item 5. Other Information

Not Applicable.

## Item 6.Exhibits

<u>Exhibit No.</u>	<u>Description</u>
31.1	* <a href="#"><u>Certification by Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2	* <a href="#"><u>Certification by Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1	** <a href="#"><u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2	** <a href="#"><u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
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.

\*\* Furnished herewith.

**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.

May 14, 2020

DELCATH SYSTEMS, INC.  
(Registrant)

/s/ Jennifer K. Simpson  
Jennifer K. Simpson  
President and Chief Executive Officer  
(Principal Executive Officer)

May 14, 2020

/s/ Barbra C. Keck  
Barbra C. Keck  
Chief Financial Officer  
(Principal Financial Officer)

## DEL CATH SYSTEMS, INC.

**PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION**  
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jennifer K. Simpson, Chief Executive Officer, 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 14, 2020

/s/ Jennifer K. Simpson  
\_\_\_\_\_  
Jennifer K. Simpson  
President and Chief Executive Officer  
(Principal Executive Officer)

## DEL CATH SYSTEMS, INC.

**PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION**  
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Barbra C. Keck, Principal Financial Officer, 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 14, 2020

/s/ Barbra C. Keck  
\_\_\_\_\_  
Barbra C. Keck  
Chief Financial Officer  
(Principal Financial Officer)



## DEL CATH SYSTEMS, INC.

**PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION**  
**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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jennifer K. Simpson, Chief Executive Officer of the Company, 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 14, 2020

/s/ Jennifer K. Simpson

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Jennifer K. Simpson  
President and Chief Executive Officer  
(Principal Executive Officer)

## DEL CATH SYSTEMS, INC.

**PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION**  
**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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barbra C. Keck, Principal Financial Officer of the Company, 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 14, 2020

/s/ Barbra C. Keck

Barbra C. Keck

Chief Financial Officer

(Principal Financial Officer)