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

FORM 10-Q

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

For the quarterly period ended June 30, 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	**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	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 August 13, 2020, 3,935,968 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 16,011	$ 10,002
Restricted cash	181	181
Accounts receivables, net	147	21
Inventories	723	654
Prepaid expenses and other current assets	1,992	1,759
Total current assets	19,054	12,617
Property, plant and equipment, net	864	735
Right-of-use assets	525	860
Total assets	$ 20,443	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,174	$ 4,533
Accrued expenses	5,429	6,947
Lease liabilities, current portion	508	664
Warrant liability	—	3,368
Total current liabilities	8,111	15,512
Deferred revenue	2,613	2,860
Lease liabilities, long-term portion	17	197
Convertible notes payable, long-term	2,000	2,000
Total liabilities	12,741	20,569
Commitments and contingencies (Note 13)	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 25,950 and 41,517 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 3,521,641 and 67,091 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively*	35	1
Additional paid-in capital	390,882	364,785
Accumulated deficit	(383,307)	(371,171)
Accumulated other comprehensive income	92	28
Total stockholders' equity (deficit)	7,702	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 20,443	$ 14,212

* 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 June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
Product revenue	$ 262	$ 221	$ 437	$ 311
Other revenue	117	191	235	371
Cost of goods sold	(168)	(172)	(246)	(268)
Gross profit	211	240	426	414
Operating expenses:				
Research and development expenses	2,223	1,714	5,197	5,011
Selling, general and administrative expenses	2,257	2,653	4,573	5,203
Total operating expenses	4,480	4,367	9,770	10,214
Operating loss	(4,269)	(4,127)	(9,344)	(9,800)
Change in fair value of the warrant liability, net	—	10	(2,832)	17
Loss on issuance of financial instrument	—	(6)	—	(6)
Interest expense	(52)	(1,837)	(109)	(4,064)
Other income	46	1	149	—
Net loss	(4,275)	(5,959)	(12,136)	(13,853)
Deemed dividend for triggering of warrant down round feature	(55)	—	(55)	—
Net loss attributable to common stockholders	$ (4,330)	$ (5,959)	$ (12,191)	$ (13,853)
Net loss	$ (4,275)	$ (5,959)	$ (12,136)	$ (13,853)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(1)	(23)	65	(74)
Total other comprehensive loss	$ (4,276)	$ (5,982)	$ (12,071)	$ (13,927)
Common share data:				
Basic loss per common share*	$ (1.90)	$ (58.50)	$ (10.40)	$ (134.55)
Diluted loss per common share*	$ (1.90)	$ (58.50)	$ (10.40)	$ (134.55)
Weighted average number of basic shares outstanding*	2,273,187	101,862	1,171,994	102,956
Weighted average number of diluted shares outstanding*	2,273,187	101,862	1,171,994	102,956

* 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' Equity (Deficit)
(Unaudited)
(in thousands, except share and per share data)

	Common Stock $0.01 Par Value		Preferred 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, 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)
Compensation expense for issuance of restricted stock	70,259	1	—	—	605	—	—	606
Conversion of Preferred stock into common stock	1,549,609	15	(15,497)	—	(16)	—	—	(1)
Exercise of prefunded warrants	6,000	—	—	—	—	—	—	—
Public Offering - issuance of common stock and warrants	1,823,000	18	—	—	19,360	—	—	19,378
Net loss	—	—	—	—	—	(4,275)	—	(4,275)
Total comprehensive loss	—	—	—	—	—	—	(1)	(1)
Balance at June 30, 2020	3,521,641	$ 35	25,950	$ —	$ 390,882	$ (383,307)	$ 92	$ 7,702

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

	Common Stock Issued $0.01 Par Value		Preferred 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, 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	—	—	—	—	—	(7,894)	—	(7,894)
Total comprehensive income	—	—	—	—	—	—	7	7
Balance at March 31, 2019	20,620	$ —	—	$ —	$ 328,113	$ (351,948)	$ 57	$ (23,778)
Compensation expense for issuance of stock options	—	—	—	—	75	—	—	75
Exercise of prefunded warrants	5,399	—	—	—	—	—	—	—
Exchange of warrants	91	—	—	—	13	—	—	13
Net loss	—	—	—	—	—	(5,959)	—	(5,959)
Total comprehensive loss	—	—	—	—	—	—	(80)	(80)
Balance at June 30, 2019	26,110	$ —	—	$ —	$ 328,201	$ (357,907)	$ (23)	$ (29,729)

*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)

	Six months ended June 30, 2020	Six months ended June 30, 2019
Cash flows from operating activities:		
Net loss	$ (12,136)	$ (13,853)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	25	129
Restricted stock compensation expense	635	4
Depreciation expense	92	122
Amortization of right of use assets	335	552
Warrant liability fair value adjustment	2,832	(17)
Loss on issuance of financial instruments	—	6
Interest expense accrued related to convertible notes	80	329
Debt discount amortization	—	3,444
Changes in assets and liabilities:		
(Increase) decrease in prepaid expenses and other assets	(232)	232
(Increase) decrease in accounts receivable	(125)	404
(Increase) decrease in inventories	(70)	143
Increase (decrease) in accounts payable and accrued expenses	(3,957)	3,827
Decrease in deferred revenue	(248)	(240)
Decrease in operating lease liabilities	(313)	(540)
Decrease in other non-current liabilities	—	(504)
Net cash used in operating activities	(13,082)	(5,962)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(221)	(2)
Net cash used in investing activities	(221)	(2)
Cash flows from financing activities:		
Principal payments on financing leases	(23)	—
Net proceeds from the issuance of debt	—	3,719
Net proceeds from sale of Series D Preferred Stock	—	150
Net payments related to reserve stock split	(106)	—
Net proceeds from Public Offering	19,378	—
Net cash provided by financing activities	19,249	3,869
Foreign currency effects on cash	63	(69)
Net increase (decrease) in cash and cash equivalents	6,009	(2,162)
Cash and cash equivalents:		
Beginning of period	10,183	3,578
End of period	$ 16,192	$ 1,416

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

	Six months ended June 30,	
	2020	**2019**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 7	$ —
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Conversions of preferred stock into common stock	$ 15	$ —
Reclassification of 2019 warrants from liability to equity	$ 6,199	$ —
Conversion of Series D preferred stock to debt	$ —	$ 1,160
Exchange of 2019 warrants	$ —	$ 13
Adoption of ASC 842 lease standard	$ —	$ 1,652
Right of use assets obtained in exchange for lease obligations	$ —	$ 874

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 and six months ended June 30, 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 CHEMOSAT® Hepatic 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 ocular melanoma liver metastases, or mOM, and the ALIGN Trial, a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma, or ICC (the "ALIGN Trial"). Our CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials or IITs.

Risks and Uncertainties

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. We expected to announce top-line data from our FOCUS trial in mid-2020; however, COVID-19 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. 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 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. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

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. All historical share and per share amounts have been retrospectively adjusted for the one-for-seven hundred stock split effected on December 24, 2019.

The preparation of interim condensed consolidated financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and cash flows for the interim periods ended June 30, 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.

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 ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. 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) Cash, Cash Equivalents and Restricted Cash

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

Cash, cash equivalents, and restricted cash balances were as follows:

(in thousands)	**June 30, 2020**	**December 31, 2019**
Cash and cash equivalents	$ 16,011	$ 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	$ 16,192	$ 10,183

(3) Inventories

Inventories consist of the following:

(in thousands)	**June 30, 2020**	**December 31, 2019**
Raw materials	$ 389	$ 375
Work-in-process	334	279
Total inventories	$ 723	$ 654

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	June 30, 2020	December 31, 2019
Clinical trial expenses	$ 1,497	$ 725
Insurance premiums	244	589
Other[1]	251	445
Total prepaid expenses and other current assets	$ 1,992	$ 1,759

[1] 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 June 30, 2020 and December 31, 2019.

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	June 30, 2020	December 31, 2019	Estimated Useful Life
Buildings and land	$ 634	$ 589	30 years - Buildings
Enterprise hardware and software	1,802	1,739	3 years
Leaseholds	1,797	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	5,467	5,246	
Accumulated depreciation	(4,603)	(4,511)	
Property, plant and equipment, net	$ 864	$ 735	

Depreciation expense for the three and six months ended June 30, 2020 was approximately $44 thousand and $92 thousand as compared to approximately $57 thousand and $122 thousand for the same periods in 2019.

(6) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	June 30, 2020	December 31, 2019
Clinical expenses	$ 2,565	$ 2,497
Compensation, excluding taxes	2,379	3,525
Other[1]	485	925
Total accrued expenses	$ 5,429	$ 6,947

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at June 30, 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.

Pursuant to a 2014 sublease agreement (the "2014 Sublease") and a 2015 sublease agreement (the "2015 Sublease") the Company subleases portions of its leased premises in Dublin, Ireland to a sublessee. On May 15, 2020, the Company and its sublessee entered into amendments to the 2014 Sublease and 2015 Sublease pursuant to which (i) the 2014 Sublease and 2015 Sublease were extended from May 31, 2020 to August 2, 2021, and (ii) effective July 1, 2020, the leased premises under the 2015 Sublease would be expanded to include an additional 4,999 square ft of space, and (ii) effective July 1, 2020, the rent under the 2015 Sublease would increase from approximately $14,559 per month to $20,643 per month. The Company analyzed the terms of the amended 2014 Sublease and 2015 Sublease and determined that its ROU for the master operating lease was not impaired as a result of the amendments.

On June 25, 2020, the Company entered into a sub-lease agreement (the "2021 Sub-Lease") with its current sublessee under the 2014 Sublease and 2015 Sublease pursuant to which, effective August 2, 2021, the current sublessee would become the lessee and the Company would then sub-lease its portion of the premises from such current sublessee. The Company Rent under the 2021 Sub-Lease will be approximately $3,721.50 per month. Aside from the 2021 Lease, the Company has no operating or financing leases that have not yet commenced.

The following table summarizes the Company's operating and financing leases as of and for the six months ended June 30, 2020:

(in thousands)	**US**	**Ireland**	**Total**
Lease cost			
Operating lease cost	$ 236	$ 103	$ 339
Financing lease cost	23	—	23
Sublease income	—	(98)	(98)
Total	$ 259	$ 5	$ 264
Other information			
Operating cash flows out from operating leases	(236)	(103)	(339)
Operating cash flows in from operating leases	-	98	98
Operating cash flows out from financing leases	(22)	—	(22)
Weighted average remaining lease term	0.7	1.1	
Weighted average discount rate - operating leases	8%	8%	

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

(in thousands)	**US**	**Ireland**	**Total**
Year ended December 31, 2020	$ 239	$ 105	$ 344
Year ended December 31, 2021	$ 78	122	200
Total	$ 317	227	544
Less present value discount	$ (9)	(10)	(19)
Operating lease liabilities included in the condensed consolidated balance sheet at June 30, 2020	$ 308	$ 217	$ 525

(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, 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 and with a July 16, 2021 maturity date, 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 July 2019 Private Placement discussed further in Notes 10 and 11 to the Company's audited consolidated financial statements contained in its Annual Report. Following the closing of the July 2019 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 notes outstanding at June 30, 2020:

	Conversion price	Current interest rate	Principal
Long term convertible notes payable			
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 E Warrants, $0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related 2019 E Warrants and issued 923 shares of Series E Preferred Stock and related 2019 E 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 December 31, 2019, the conversion price was $23.04 and was subsequently adjusted to $10.00 upon the pricing of a $22.0 million offering on May 5, 2020, as discussed further below. As a result of the price adjustment, the excess of the fair value of the common stock that will be received on conversion, measured on the price reset date, exceeded the original proceeds allocated to the Preferred Stock by $12.0 million. 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 December 31, 2019. The exercise price was subsequently adjusted to $10.00 upon the pricing of a $22.0 million offering on May 5, 2020, as discussed further below, which resulted in the recognition of a $55 thousand deemed dividend. The 2019 Warrants are exercisable until 5:00 p.m. (NYC time) on December 24, 2024.

As of June 30, 2020, there were 25,950 shares of Preferred Stock outstanding and 1.8 million 2019 Warrants outstanding.

Public Offering and Nasdaq Uplisting

On May 5, 2020, the Company closed a public offering of 1,823,000 shares of common stock, 377,000 pre-funded warrants and Series F warrants to purchase 2,224,900 shares of common stock at an exercise price of $10.00 per share. 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 Preferred Stock conversion price was adjusted to $10.00 and the exercise price of the 2019 Warrants was adjusted to $10.00 and neither instrument is subject to further price resets.

Other Common Stock Issuances

During the six months ended June 30, 2020 the Company issued 1,549,609 shares of the Company's common stock pursuant to conversions of Preferred Stock.

During the six months ended June 30, 2020, the Company issued 6,000 shares of common stock associated with the exercise of pre-funded warrants.

During the six months ended June 30, 2020, the Company issued 72,976 shares of common stock as compensation.

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 June 30, 2020, the Plan had approximately 502 shares available for grant.

The following is a summary of stock option activity under the Plan for the six months ended June 30, 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 June 30, 2020	1,640	$ 196.70	8.6	$ —
Exercisable at June 30, 2020	1,640	$ 196.70	8.6	$ —

At June 30, 2020, there was no unrecognized compensation expense related to non-vested share-based compensation awards under the Plan. The following is a summary of share-based compensation expense in the statement of operations:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2020	2019	2020	2019
Selling, general and administrative	$ 606	$ 58	$ 655	$ 106
Research and development	—	17	5	27
Total	$ 606	$ 75	$ 660	$ 133

Warrants

The following is a summary of warrant activity for the six months ended June 30, 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	2,601,900		10.00	
Exercised	(6,000)		0.01	
Expired	(9)		7.00	
Outstanding at June 30, 2020	4,422,499	$0.01- $10.00	$ 9.16	4.7

As of June 30, 2020, warrants to purchase 371,000 shares of 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 2019 Warrants 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 six months ended June 30, 2020:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	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 June 30, 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 June 30, 2020, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
(in thousands)	Level 1		Level 2		Level 3		Total	
	June 30, 2020	December 31, 2019	June 30, 2020	December 31, 2019	June 30, 2020	December 31, 2019	June 30, 2020	December 31, 2019
Liabilities								
Derivative instrument liabilities	$ —	$ —	$ —	$ —	$ —	$ 3,368	$ —	$ 3,368

(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 June 30, 2020 and 2019 because their effects would be anti-dilutive:

	June 30,	
(in thousands, except share data)	2020	2019
Stock options	1,640	1,667
Common stock warrants - equity	4,051,499	6,004
Common stock warrants - liabilities	—	179
Common stock reserved for conversion of preferred shares	2,595,087	—
Assumed conversion of convertible notes	146,288	480
Total	6,794,514	8,329

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 table reconciles net loss per share for the three and six months ended June 30, 2020 and 2019:

	Three months ended June 30,		Six months ended June 30,	
(in thousands, except share data)	2020	2019	2020	2019
Net loss	$ (4,275)	$ (5,959)	$ (12,136)	$ (13,853)
Deemed dividend for triggering of warrant down round feature	(55)	—	(55)	—
Net loss attributable to common stockholders	$ (4,330)	$ (5,959)	$ (12,191)	$ (13,853)
Weighted average shares outstanding - basic*	2,273,187	101,862	1,171,994	102,956
Weighted average shares outstanding - diluted*	2,273,187	101,862	1,171,994	102,956
Net loss per share - basic*	$ (1.90)	$ (58.50)	$ (10.40)	$ (134.55)
Net loss per share - diluted*	$ (1.90)	$ (58.50)	$ (10.40)	$ (134.55)

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

At June 30, 2020, 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 and six months ended June 30, 2020 and 2019:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Weighted average shares issued	2,038,297	25,587	1,054,549	26,681
Weighted average pre-funded warrants	234,890	76,275	117,445	76,275
Weighted average shares outstanding	2,273,187	101,862	1,171,994	102,956

(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.

During the six months ending June 30, 2020, the Company settled intercompany debt of its two Ireland subsidiaries, Delcath Systems Limited and Delcath Holdings Limited, as capital contributions. During the six months ending June 30, 2020, Delcath Holdings Limited ceased operations with an intent to liquidate after the receipt of tax clearance. When Delcath Holdings Limited liquidates, the Company will generate a $19.9 million U.S. deferred tax benefit from a loss on its investment, which may be subject to limitations under Internal Revenue Code Sections 382 and 383 and will be fully offset by a valuation allowance.

(13) Commitments and Contingencies

Following the May 18, 2020 resignation 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 $1.14 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. As of June 30, 2020, the Company has accrued for the full purported unpaid compensation amounts.

(14) Subsequent Events

Preferred Stock Conversions

Subsequent to June 30, 2020, the Company issued 372,500 shares of the Company's common stock upon the conversion of Preferred Stock.

Property Purchase

On July 31, 2020, the Company exercised its option to purchase its 95-97 Park Road office location in Queensbury, NY for $460,263, 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.

Stock Warrant Exercises

Subsequent to June 30, 2020, warrants to purchase 41,827 shares of the Company's common stock with an exercise price of $10.00 per share were exercised for proceeds of $418,270.

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, 2019 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 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 on Form 10-K 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 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 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 on Form 10-K 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, where it has been used at major medical centers to treat a wide range of cancers of the liver.

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 (one for doxorubicin in hepatocellular indication and five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma and neuroendocrine tumor indications), 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 European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Recent Developments

COVID-19

The COVID-19 pandemic has affected many countries, including the United States and several European countries, where we are currently conducting our FOCUS Trial and ALIGN Trial. In response to the pandemic, hospitals participating in the trials in affected countries have taken a number of actions, including restricting elective and other procedures that are not deemed to be life-threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials have had the start of their treatments postponed and ongoing treatment regimens may be delayed. In addition, we do not have sufficient access to monitor trial data on a timely basis. These restrictions have had a materially adverse effect on our clinical operations. We expected to announce top-line data from our FOCUS trial in mid-2020. 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.

The extent to which the COVID-19 pandemic may affect our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the spread and severity of COVID-19, and the effectiveness of governmental actions in response to the pandemic. Furthermore, the spread of COVID-19 may materially and adversely affect our ability to recruit and retain patients.

We expect that actions taken in response to the COVID-19 pandemic will also materially and adversely affect sales of CHEMOSAT. As noted above, some hospitals are restricting procedures that are not deemed to be life-threatening at this time. Because CHEMOSAT is not deemed to be an essential procedure, we expect that the number of procedures performed could decline. While we do not expect revenues from CHEMOSAT procedures to be material to us, a decrease in the number of procedures performed would adversely affect our expected revenues and our financial results.

These consequences of the COVID-19 pandemic will delay and could adversely affect our ability to obtain regulatory approval for and to commercialize our products, increase our operating expenses, and could have a material adverse effect on our financial results. The situation continues to rapidly change and additional impacts to 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.

Public Offering

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

Three Months Ended June 30, 2020 Compared with Three Months Ended June 30, 2019

Revenue

We had revenue of approximately $0.4 million for the three months ended June 30, 2020 compared to $0.4 million for the three months ended June 30, 2019.

Cost of Goods Sold

For the three months ended June 30, 2020, we recorded cost of goods sold of approximately $0.2 million compared to $0.2 million for the three months ended June 30, 2019.

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 June 30, 2020 and 2019, research and development expenses increased to $2.2 million from $1.7 million. The increase was primarily due to our FOCUS trial becoming 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 June 30, 2020 and 2019, selling, general and administrative expenses were $2.3 million and $2.7 million, respectively. The decrease is primarily related to reduced personnel expenses as a result of reduced headcount.

Other Income/Expense

Other income and expense is primarily related to the amortization of debt discounts and the interest on convertible notes. For the three months ended June 30, 2020, interest expense decreased $1.8 million compared to the three months ended June 30, 2019. The decrease in the note principal balance from $10.5 million at June 30, 2019 to $2.0 million at June 30, 2020 is the primary reason for the decrease in interest expense.

Net Loss

Our net loss for the three months ended June 30, 2020 was $4.3 million, a decrease of $1.7 million compared to net loss of $6.0 million for the three months ended June 30, 2019. The decrease in net loss is primarily due to the $1.8 million decrease in interest expense on the convertible notes discussed above.

Six Months Ended June 30, 2020 Compared with Six Months Ended June 30, 2019

Revenue

We had revenue of approximately $0.7 million for the six months ended June 30, 2020 compared to $0.7 million for the six months ended June 30, 2019.

Cost of Goods Sold

For the six months ended June 30, 2020, we recorded cost of goods sold of approximately $0.2 million compared to $0.3 million for the six months ended June 30, 2019.

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 six months ended June 30, 2020 and 2019, research and development expenses increased to $5.2 million from $5.0 million. The increase was primarily due to our FOCUS trials becoming 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 six months ended June 30, 2020 and 2019, selling, general and administrative expenses were $4.6 million and $5.2 million, respectively. The decrease is primarily related to reduced personnel expenses as a result of reduced headcount.

Other Income/Expense

Other income and expense is primarily related to the amortization of debt discounts and the interest on convertible notes, plus the change in fair value of the warrant liability. For the six months ended June 30, 2020, interest expense decreased $4.0 million compared to June 30, 2019. The decrease in the note principal balance from $10.5 million at June 30, 2019 to $2.0 million at June 30, 2020 is the primary reason for the decrease in interest expense. In addition, we recorded a $2.8 million charge during the six months ended June 30, 2020 (with no such prior period charge), due to the change in the fair value of the warrant liability.

Net Loss

Our net loss for the six months ended June 30, 2020 was $12.1 million, a decrease of $1.8 million, compared to the net loss of $13.9 million for the six months ended June 30, 2019. The decrease in net loss is primarily due to the $4.0 million decrease in interest expense related to the convertible notes, partially offset by the $2.8 million change in fair value of the warrant liability.

Liquidity and Capital Resources

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 our operations.

At June 30, 2020, we had cash, cash equivalents and restricted cash totaling $16.2 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $1.4 million at June 30, 2019. During the six months ended June 30, 2020 and 2019, we used $13.1 million and $6.0 million, respectively, of cash in our operating activities.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and 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 (GAAP). During the six months ended June 30, 2020, 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, 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 our 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 were subject to mark-to-market adjustments each period and were reclassified to equity during the first quarter of 2020. During the six months ended June 30, 2020, we recorded a 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 June 30, 2020. Management expects that the warrants outstanding at June 30, 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

The Company's management, with the participation of our Interim 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 Interim Chief Executive Officer and Interim Principal Accounting Officer concluded that our disclosure controls and procedures as of June 30, 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 Interim 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 June 30, 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.

Following the May 18, 2020 resignation 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 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 fiscal year ended December 31, 2019.

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

On May 6, 2020, the Company issued an aggregate of 70,259 shares of unregistered Common Stock, consisting of (i) 22,963 shares of unregistered Common Stock to the executive officers of the Company (the "Executives") pursuant to the terms of a Support and Conversion Agreement, dated March 11, 2020 and amended on April 8, 2020, among the Company, the Executives and the other parties thereto, in lieu of paying certain accrued bonus amounts to the Executive Officers in an aggregate amount of $221,000, and (ii) 47,296 shares of unregistered Common Stock to Encode Ideas, L.P. ("Encode") in relation to certain advisory services provided to the Company, 25,283 of which shares were issued pursuant to the Company's obligation to issue shares to Encode in connection with the Company's original retention of that firm, and 22,013 of which shares were issued in lieu of paying in cash a $175,000 fee for research services which came due prior to that date. In each case the Company relied upon the exemption provided in Section 4(a)(2) of the Securities Act of 1933 and Rule 506 of Regulation D thereunder, as each of the Executive Officers and Encode are "accredited investors" as defined in Rule 501(d) of Regulation D.

Item 3.Defaults upon Senior Securities

None.

Item 4.Mine Safety Disclosures

Not Applicable.

Item 5.Other Information

None.

Item 6.Exhibits

Exhibit No.		Description
4.1		Form of Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC, including the form of Series F warrant (incorporated by reference to Exhibit 4.8 of the Company's Form S-1/A filed on April 20, 2020)***
10.1		Board Appointment Agreement dated as of April 8, 2020 among the Company and the other parties thereto. (incorporated by reference to Exhibit 10.57 of the Company's Form S-1/A filed on April 20, 2020)***
10.2		Support and Conversion Agreement dated as of March 11, 2020 among the Company and the other parties thereto (incorporated by reference to Exhibit 10.55 to the Company's Form S-1/A filed on April 20, 2020), as amended by Amendment to Support and Conversion Agreement dated as of April 8, 2020 among the Company and the other parties thereto (incorporated by reference to Exhibit 10.56 to the Company's Form S-1/A filed on April 20, 2020)***
31.1	*	Certification by Interim 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 Interim 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.

** Furnished herewith.

*** Previously filed.

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.

August 13, 2020	DELCATH SYSTEMS, INC.
	/s/ John Purpura John Purpura Interim Chief Executive Officer
August 13, 2020	/s/ Christine Padula Christine Padula Interim Principal Accounting Officer

DELCATH SYSTEMS, INC.

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

I, John Purpura, certify that:

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

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

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

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

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

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

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

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

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

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

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

August 13, 2020

/s/ John Purpura
John Purpura
Interim 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.

August 13, 2020

/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 June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Purpura, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

August 13, 2020

/s/ John Purpura
John Purpura
Interim 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 June 30, 2020, 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.

August 13, 2020

/s/ Christine Padula
Christine Padula
Interim Principal Accounting Officer