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 September 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 November 12, 2020, 4,116,754 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)

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 10,899	$ 10,002
Restricted cash	181	181
Accounts receivables, net	103	21
Inventories	839	654
Prepaid expenses and other current assets	1,860	1,759
Total current assets	13,882	12,617
Property, plant and equipment, net	1,318	735
Deferred offering costs	268	—
Right-of-use assets	1,097	860
Total assets	$ 16,565	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,502	$ 4,533
Accrued expenses	6,085	6,947
Deferred revenue, current	501	482
Lease liabilities, current	556	664
Convertible notes payable, current	2,000	—
Warrant liability	—	3,368
Total current liabilities	10,644	15,994
Deferred revenue, non-current	2,103	2,378
Lease liabilities, non-current	542	197
Convertible notes payable, non-current	—	2,000
Total liabilities	13,289	20,569
Commitments and contingencies (Note 13)	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 21,473 and 41,517 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 4,035,558 and 67,091 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively*	40	1
Additional paid-in capital	391,545	364,785
Accumulated deficit	(388,298)	(371,171)
Accumulated other comprehensive income	(11)	28
Total stockholders' equity (deficit)	3,276	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 16,565	$ 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 September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Product revenue	$ 340	$ 216	$ 778	$ 528
Other revenue	126	164	361	535
Cost of goods sold	(188)	(172)	(434)	(440)
Gross profit	278	208	705	623
Operating expenses:				
Research and development expenses	3,260	1,778	8,457	6,789
Selling, general and administrative expenses	1,998	4,002	6,571	9,204
Total operating expenses	5,258	5,780	15,028	15,993
Operating loss	(4,980)	(5,572)	(14,323)	(15,370)
Change in fair value of the warrant liability, net	—	434	(2,832)	451
Loss on issuance of financial instrument	—	(1,714)	—	(1,721)
Interest expense	(44)	(671)	(154)	(4,735)
Other income	33	4	182	4
Net loss	(4,991)	(7,519)	(17,127)	(21,371)
Deemed dividend for triggering of warrant down round feature	—	—	(55)	—
Net loss attributable to common stockholders	$ (4,991)	$ (7,519)	$ (17,182)	$ (21,371)
Net loss	$ (4,991)	$ (7,519)	$ (17,127)	$ (21,371)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(103)	89	(39)	39
Total other comprehensive loss	$ (5,094)	$ (7,430)	$ (17,166)	$ (21,332)
Common share data:				
Basic loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Diluted loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Weighted average number of basic shares outstanding*	4,288,593	101,862	2,217,611	102,956
Weighted average number of diluted shares outstanding*	4,288,593	101,862	2,217,611	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
Conversion of Preferred stock into common stock	447,700	4	(4,477)	—	(4)	—	—	—
Exercise of warrants into common stock	60,117	1	—	—	601	—	—	602
ATM Offering	6,100	—	—	—	66	—	—	66
Net loss	—	—	—	—	—	(4,991)	—	(4,991)
Total comprehensive loss	—	—	—	—	—	—	(103)	(103)
Balance at September 30, 2020	4,035,558	$ 40	21,473	$ —	$ 391,545	$ (388,298)	$ (11)	$ 3,276

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)
Compensation expense for issuance of stock options	—	—	—	—	70	—	—	70
Issuance of Series E Preferred Stock	—	—	32,572	—	42,915	(13,340)	—	29,575
Issuance of Series E-1 Preferred Stock	—	—	9,510	—	14,408	(4,898)	—	9,510
Fair value of warrants issued	—	—	—	—	(20,844)	—	—	(20,844)
Net loss	—	—	—	—	—	(7,519)	—	(7,519)
Total comprehensive loss	—	—	—	—	—	—	112	112
Balance at September 30, 2019	26,110	$ —	42,082	$ —	$ 364,750	$ (383,664)	$ 89	$ (18,825)

*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)

	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (17,127)	$ (21,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	25	199
Restricted stock compensation expense	406	4
Depreciation expense	125	168
Amortization of right of use assets	492	1,535
Warrant liability fair value adjustment	2,832	(451)
Non-cash interest income	—	(23)
Equitization of expenses	—	1,474
Loss on issuance of financial instruments	—	1,715
Interest expense accrued related to convertible notes	120	33
Debt discount amortization	—	4,467
Changes in assets and liabilities:		
(Increase) decrease in prepaid expenses and other assets	(100)	43
(Increase) decrease in accounts receivable	(82)	564
(Increase) decrease in inventories	(185)	85
Increase in deferred offering costs	(268)	—
Decrease in accounts payable and accrued expenses	(3,784)	(4,289)
Decrease in deferred revenue	(256)	(360)
Decrease in operating lease liabilities	(466)	(1,488)
Decrease in other liabilities	—	(627)
Net cash used in operating activities	(18,268)	(18,322)
Cash flows from investing activities:		
Purchase of property, plant, and equipment	(708)	(2)
Net cash used in investing activities	(708)	(2)
Cash flows from financing activities:		
Principal payments on financing leases	(26)	(49)
Net proceeds from the issuance of debt	—	3,719
Net proceeds from sale of Series D Preferred Stock	—	150
Net proceeds from sale of Series E Preferred Stock and warrants	—	26,510
Net payments related to reverse stock split	(106)	—
Net proceeds from Public Offering	19,377	—
Net proceeds from the exercise of warrants	601	—
Gross proceeds from ATM Offering	70	—
Issuance costs related to ATM Offering	(4)	—
Net cash provided by financing activities	19,912	30,330
Foreign currency effects on cash	(39)	(69)
Net increase in total cash	897	11,937
Total Cash:		
Beginning of period	10,183	3,578
End of period	$ 11,080	$ 15,515

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

	Nine months ended September 30,	
	2020	**2019**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the periods for:		
Interest expense	$ 7	$ 4
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Conversions of Preferred Stock into common stock	$ 20	$ —
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
Fair value of warrants issued		$ 20,844
Adoption of ASC 842 lease standard		$ 1,652
Right of use assets obtained in exchange for lease obligations	$ 729	$ 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 nine months ended September 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. Delcath's proprietary technology enables the administration of high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO™, is currently the focus of a Phase 3 pivotal trial. HEPZATO is a combination drug device product regulated as a drug product by the United States Food and Drug Administration, or the FDA. In Europe, the device is commercially available as a stand-alone device without drug 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 HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial in metastatic ocular melanoma, or mOM, and the ALIGN Trial, a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma, or ICC (the "ALIGN Trial"). The FOCUS trial initiated treatment on the final enrolled patient on October 2, 2020. Presently, we have paused our work on the ALIGN trial while we reevaluate the trial design and are focusing our efforts on the FOCUS trial conclusion and subsequent NDA filing. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications which will maximize the value of the HEPZATO platform. Whether we continue the ALIGN trial will be dependent on the relative value of the ICC indication versus other alternative indications. In addition, 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

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

Liquidity and Going Concern

The accompanying interim condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and expects to continue incurring losses for the next several years. These losses, among other factors, raise substantial doubt about the Company's ability to continue as a going concern.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. 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 reverse 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 September 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

There have been no material changes to our significant accounting policies as set forth in Note 3 Summary of Significant Accounting Policies to the consolidated financial statements included in the Company's Annual Report, except for the following:

Deferred Offering Costs

Deferred offering costs are expenses directly related to an at-the-market offering of the Company's common stock (the "ATM Offering") (see Note 9), which is pursuant to a prospectus supplement which is part of a shelf registration that was declared effective by the SEC on December 31, 2018 (the "Shelf Registration"). These costs consist of legal, accounting, printing, and filing fees that the Company has capitalized, including fees incurred by the independent registered public accounting firm directly related to the offerings. Deferred costs associated with the ATM Offering will be amortized to additional paid in capital on a pro-rata basis as the Company raises funds pursuant to the ATM Offering, with any remaining deferred offering costs charged to the results of operations at the end of the life of the Shelf Registration. As of September 30, 2020, the unamortized deferred offering costs were $268.0.

Reclassifications

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

Recently 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)	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 10,899	$ 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	$ 11,080	$ 10,183

(3) Inventories

Inventories consist of the following:

(in thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 376	$ 375
Work-in-process	463	279
Total inventories	$ 839	$ 654

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	September 30, 2020	December 31, 2019
Clinical trial expenses	$ 1,497	$ 725
Insurance premiums	63	589
Other[1]	300	445
Total prepaid expenses and other current assets	$ 1,860	$ 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 September 30, 2020 and December 31, 2019.

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)		September 30, 2020		December 31, 2019	Estimated Useful Life
Buildings and land	$	1,109	$	589	30 years - Buildings
Enterprise hardware and software		1,805		1,739	3 years
Leaseholds		1,808		1,695	Lesser of lease term or estimated useful life
Equipment		1,045		1,025	7 years
Furniture		203		198	5 years
Property, plant, and equipment, gross		5,970		5,246	
Accumulated depreciation		(4,652)		(4,511)	
Property, plant and equipment, net	$	1,318	$	735	

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

Depreciation expense for the three and nine months ended September 30, 2020 was approximately $32.7 and $124.7 as compared to approximately $45.8 and $168.0 for the same periods in 2019.

(6) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)		September 30, 2020		December 31, 2019
Clinical expenses	$	2,919	$	2,497
Compensation, excluding taxes		2,499		3,525
Other[1]		667		925
Total accrued expenses	$	6,085	$	6,947

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

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

(in thousands)	US	Ireland	Total
Lease cost			
Operating lease cost	$ 353	$ 156	$ 509
Financing lease cost	27	—	27
Sublease income	—	(162)	(162)
Total	$ 380	$ (6)	$ 374
Other information			
Operating cash flows out from operating leases	(353)	(156)	(509)
Operating cash flows in from operating leases	-	162	162
Operating cash flows out from financing leases	(26)	—	(26)
Right-of-use assets exchanged for new operating lease liabilities	729	—	729
Weighted average remaining lease term	2.4	0.8	
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	$ 118	$ 55	$ 173
Year ended December 31, 2021	416	128	544
Year ended December 31, 2022	406	-	406
Year ended December 31, 2023	68	-	68
Total	1,008	183	1,191
Less present value discount	(86)	(7)	(93)
Operating lease liabilities included in the condensed consolidated balance sheets at September 30, 2020	$ 922	$ 176	$ 1,098

(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 $2,000 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 in Note 9 herein and 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, on the condensed consolidated balance sheet.

(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 $11,800 of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and related 2019 E Warrants, $100 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 $21,996 public offering of the Company’s common stock and warrants 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 $12,000. 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 per share at December 31, 2019. The exercise price was subsequently adjusted to $10.00 per share upon the pricing of a $21,996 offering on May 5, 2020, as discussed further below, which resulted in the recognition of a $54.5 deemed dividend. The 2019 Warrants are exercisable until 5:00 p.m. (NYC time) on December 24, 2024.

As of September 30, 2020, there were 21,473 shares of Preferred Stock outstanding and 1,826,579 2019 Warrants outstanding.

Public Offering

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 (the “Public Offering”). Delcath received gross proceeds of approximately $21,996 from the offering, before deducting the underwriting discount and estimated offering expenses. As a result of the Public Offering, the Preferred Stock conversion price was adjusted to $10.00 per share and the exercise price of the 2019 Warrants was adjusted to $10.00 per share and neither instrument is subject to further price resets.

At-the-Market Offering

On August 18, 2020, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, as sales agent or principal, shares of the Company’s common stock, (the “Placement Shares”), having an aggregate offering price of up to $10,000 (the “ATM Offering”). The Company has no obligation to sell any Placement Shares under the sales agreement. Subject to the terms and conditions of the sales agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Stock Market, to sell Placement Shares from time to time based upon the Company’s instructions, including any price, time or size limits specified by the Company. The Company will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of Placement Shares, reimburse Cantor Fitzgerald’s legal fees and disbursements up to $50.0 and provide Cantor Fitzgerald with customary indemnification and contribution rights. The sales agreement may be terminated by Cantor Fitzgerald or the Company upon notice to the other party as provided in the sales agreement, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in the Company’s business or financial condition that makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares.

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

Rosalind Master Fund L.P. and Rosalind Opportunities Fund I L.P. (together, “Rosalind”) waived, solely with respect to the ATM Offering, Rosalind’s right, pursuant to that certain Support and Conversion Agreement dated March 11, 2020 between Rosalind and the Company, as amended, to participate in any offer or sale of the Company’s common stock by the Company occurring within a two-year period.

On August 18, 2020, the Company and the holders of a requisite number of shares of the Company’s Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock and related warrants (the “Holders”) entered into an Amendment to those certain Securities Purchase Agreements, dated July 11, 2020 and August 15, 2019, among the Company and the parties signatory thereto, for the purpose of clarifying that offerings of the Company’s common stock in “at the market” transactions are excluded from the rights of the holders set forth therein.

Through September 30, 2020, the Company sold 6,100 shares of common stock for aggregate gross proceeds of $70.5 pursuant to the ATM Offering.

Other Common Stock Issuances

During the nine months ended September 30, 2020 the Company issued 2,000,224 shares of the Company’s common stock pursuant to conversions of Preferred Stock.

During the nine months ended September 30, 2020, the Company issued 6,000 shares of common stock associated with the exercise of pre-funded warrants and 60,117 shares of common stock associated with other warrants.

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

2020 Omnibus Equity Incentive Plan

On September 30, 2020 (the “Effective Date”), the Company’s 2020 Omnibus Equity Incentive Plan (the “2020 Plan”) was adopted by the Company’s Board of Directors. If subsequently approved by the Company’s stockholders, the 2020 Plan will continue in effect until the tenth anniversary of the Effective Date, or until earlier terminated by the Board. The 2020 Plan will be administered by the Board of Directors or a committee designated by the Board of Directors. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, as well as other stock-based awards or cash awards that are deemed to be consistent with the purposes of the plan to Company employees, directors and consultants. There are 675,000 shares of common stock reserved under the 2020 Plan, of which all remained available to be issued as of September 30, 2020 (see Note 14 – Subsequent Events – Option Grants for details of awards granted on October 1, 2020). Upon stockholder approval of the 2020 Plan, no further grants of awards will be made under the 2019 Equity Incentive Plan.

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 September 30, 2020, the Plan had approximately 1,643 shares available for grant.

The following is a summary of stock option activity under the Plan for the nine months ended September 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	(1,141)					
Outstanding at September 30, 2020	499	$	196.70	8.4	$	—
Exercisable at September 30, 2020	499	$	196.70	8.4	$	—

At September 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 for the three and nine months ended September 30, 2020

	Three months ended September 30,				Nine months ended September 30,			
(in thousands)	2020		2019		2020		2019	
Selling, general and administrative	$	—	$	54	$	655	$	160
Research and development		—		16		5		43
Total	$	—	$	70	$	660	$	203

Warrants

The following is a summary of warrant activity for the nine months ended September 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	(66,117)			9.09	
Expired	(18)			7.00	
Outstanding at September 30, 2020	4,362,373	$0.01- $10.00	$	9.15	4.5

As of September 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. Each 2019 Warrant had an exercise price equal to $23.04 per share at December 31, 2019. The exercise price was subsequently adjusted to $10.00 per share upon the pricing of a $22,000 offering on May 5, 2020, as discussed below, which resulted in the recognition of a $54.5 deemed dividend.

(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 nine months ended September 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 September 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 September 30, 2020, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

(in thousands)	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Total	
	September 30, 2020	December 31, 2019	September 30, 2020	December 31, 2019	September 30, 2020	December 31, 2019	September 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 September 30, 2020 and 2019 because their effects would be anti-dilutive:

	September 30, 2020	September 30, 2019
Stock options	499	1,643
Common stock warrants - equity	3,991,373	-
Common stock warrants - liabilities	—	1,001,962
Common stock reserved for conversion of preferred shares	2,147,394	1,001,962
Assumed conversion of convertible notes	146,288	31,746
Total	6,285,554	2,037,313

The following table reconciles net loss per share for the three and nine months ended September 30, 2020 and 2019:

(in thousands, except share data)	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Net loss	$ (4,991)	$ (7,519)	$ (17,127)	$ (21,371)
Deemed dividend for triggering of warrant down round feature	—	—	(55)	—
Net loss attributable to common stockholders	$ (4,991)	$ (7,519)	$ (17,182)	$ (21,371)
Weighted average shares outstanding - basic*	4,288,593	101,862	2,217,611	102,956
Weighted average shares outstanding - diluted*	4,288,593	101,862	2,217,611	102,956
Net loss per share - basic*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Net loss per share - diluted*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)

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

At September 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 nine months ended September 30, 2020 and 2019:

	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Weighted average shares issued	3,917,593	25,587	2,015,863	26,681
Weighted average pre-funded warrants	371,000	76,275	201,748	76,275
Weighted average shares outstanding	4,288,593	101,862	2,217,611	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 sheets.

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 nine months ended September 30, 2020 the Company settled intercompany debt of its two Ireland subsidiaries, Delcath Systems Limited and Delcath Holdings Limited, as capital contributions. During the nine months ended September 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 $20,000 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

Litigation, Claims and Assessments

Following the May 18, 2020 resignation (effective June 1, 2020) of Jennifer Simpson, the Company's former President and Chief Executive Officer, and Barbra Keck, the Company's former Chief Financial Officer (the "Claimants"), it became evident that there was a dispute regarding the Company's compensation obligations to the Claimants. In a letter dated, June 29, 2020, an attorney representing the Claimants made certain claims and threatened litigation against the Company. On or about July 27, 2020, the Claimants filed a statement of claim with the American Arbitration Association against the Company. The Claimants seek payment of certain purported unpaid compensation amounts claimed to be due to them, in an approximate amount of $1,140 in the aggregate, as well as unspecified statutory damages under New York Labor Law, attorneys' fees and costs, and statutory interest. The Company intends to defend the claims vigorously. The arbitrator has scheduled hearings to take place during the week of May 17, 2021. However, the Claimants and the Company have recently agreed to participate in non-binding mediation of their dispute before a neutral mediator, which will result in the arbitration proceedings being placed in abeyance pending the outcome of the mediation process. At this time, the Company is unable to predict the timing for the mediation process, nor whether mediation will result in an amicable resolution of its dispute with the Claimants. As of September 30, 2020, the Company has accrued for the full purported unpaid compensation amounts.

Operating Leases

Pursuant to a 2014 sublease agreement (the "2014 Sublease") and a 2015 sublease agreement (the "2015 Sublease") the Company subleased 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, (ii) effective July 1, 2020, the leased premises under the 2015 Sublease would be expanded to include an additional 4,999 square feet of space, and (iii) effective July 1, 2020, the rent under the 2015 Sublease would increase from approximately $14.6 per month to $20.6 per month. The Company analyzed the terms of the amended 2014 Sublease and 2015 Sublease and determined that its ROU asset 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 the current sublessee. The Company rent under the 2021 Sub-Lease will be approximately $3.7 per month for a term of five years. Aside from the 2021 Sub-Lease, the Company has no operating or financing leases that have not yet commenced.

On September 22, 2020, the Company entered into an amendment (the "Second Amendment to Sublease") to a sub-lease agreement executed in March 2016 for approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term began in April 2016 and under the terms of the Second Amendment to Sublease is extended through February 2023 and provides for total annual base rent of $405.7.

(14) Subsequent Events

Stock Warrant Exercises

Subsequent to September 30, 2020, warrants to purchase 9,653 shares of the Company's common stock with an exercise price of $10.00 per share were exercised for proceeds of $93.5.

Common Stock Sold - ATM Offering

Subsequent to September 30, 2020 71,544 shares of the Company's common stock were sold in the ATM Offering at the prevailing market prices for proceeds of $814.7.

Officer Appointment – Chief Executive Officer

On October 1, 2020, Gerard Michel was appointed as the Company's new Chief Executive Officer and a Class I Director. Pursuant to an employment agreement dated as of August 31, 2020 between the Company and Mr. Michel (the "Employment Agreement"), the term of Mr. Michel's employment began on October 1, 2020. Under the Employment Agreement, Mr. Michel will receive an annual base salary of $450 subject to annual review by the Board's Compensation and Stock Option Committee, and will be eligible to participate in the Company's annual incentive plan with a target annual cash bonus equal to 50% of his then-current base salary. In addition, the Company will reimburse Mr. Michel up to $6.5 per month to cover his temporary expenses incurred in connection with traveling to and living in the New York City tristate area to work onsite at the Company's principal corporate office for the initial eighteen (18) months of his employment.

Pursuant to the Employment Agreement, on October 1, 2020, the Company granted to Mr. Michel a nonqualified and non-plan stock option to purchase 498,000 shares of the Company's common stock. The option vests ratably over a 36-month period. The exercise price of the option is equal to (i) $11.67 per share , the closing trading price per share of the Company's common stock on October 1, 2020 as to the first 396,000 option shares to vest, (ii) 1.5 times the closing trading price per share of the Company's common stock on October 1, 2020 as to the next 51,000 option shares to vest and (iii) 2.0 times the closing trading price per share of the Company's common stock on October 1, 2020 as to the remaining 51,000 option shares to vest.

If Mr. Michel resigns his at-will employment for Good Reason, as defined, or the Company terminates Mr. Michel's employment other than for Cause, as defined, then Mr. Michel shall be entitled to his accrued and unpaid compensation and, subject to him entering into and not revoking a general release of claims in favor of the Company and fully complying with the terms of an Employee Confidentiality, Invention Assignment and Restrictive Covenants Agreement (the "Restrictive Covenants Agreement"), Mr. Michel shall also be entitled to: (a) a severance payment equal in the aggregate to twelve (12) months of his annual base salary at the time of termination, payable in twelve (12) equal monthly installments; and (b) specified continuing health plan benefits until the earlier of (i) the twelve (12) month anniversary of his termination date; (ii) the last day he's eligible for coverage pursuant to COBRA; or (iii) the date on which he becomes eligible for similar coverage from another employer.

Officer Appointment – Chief Operating Officer

On October 1, 2020, John Purpura was elevated to the position of Chief Operating Officer and he resigned from his position as the Company's Interim Chief Executive Officer. In connection with his promotion, Mr. Purpura will be paid an annual base salary of $385 and will have an annual bonus opportunity of up to 45% of his annual base salary.

Option Grants

On October 1, 2020, the Company granted ten-year options to directors and employees to purchase an aggregate of 550,000 shares of common stock at an exercise price of $11.67 per share, subject to shareholder approval of the pending 2020 Plan. The options vest ratably on a monthly basis over 36 months.

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 HEPZATO, generate revenue and successfully obtain reimbursement for the procedure and Delcath Hepatic Delivery system;
- the progress and results of our research and development programs;
- our expectations about the COVID-19 pandemic and any potential disruption or impact to our operations;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and HEPZATO;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

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, the HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO™, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, HEPZATO is approved for sale under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used as a stand-alone device at major medical centers to treat a wide range of cancers of the liver.

Our research and development efforts are primarily focused on ocular melanoma liver metastases. There are numerous other cancers which metastasize to the liver and for which there is a high unmet medical need. Follow-on indications under strategic assessment include intrahepatic cholangiocarcinoma, metastatic neuroendocrine tumors, metastatic breast cancer and metastatic colorectal cancers.

Our clinical development program ("CDP") for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM, and the ALIGN Trial, a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma, or ICC (the "ALIGN Trial"). The FOCUS trial initiated treatment on the final enrolled patient on October 2, 2020. Presently, we have paused our work on the ALIGN trial while we reevaluate the trial design and in order to be able to concentrate our efforts on the FOCUS trial conclusion and subsequent NDA filing. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications which will maximize the value of the HEPZATO platform. Whether we continue the ALIGN trial will be dependent on the relative value of the ICC indication versus other alternative indications. In addition, our CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials or IITs.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. The FDA has granted Delcath six orphan drug designations (five for melphalan in ocular melanoma, cutaneous melanoma, cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the hepatocellular carcinoma indication). HEPZATO 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 hepatic delivery 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

Strengthening of Leadership Team

The Company's Board of Directors appointed Gerard Michel as the Chief Executive Officer of the Company, effective October 1, 2020. Mr. Michel also serves as a member of the Company's Board of Directors. Prior to joining the Company, Mr. Michel was the Chief Financial Officer and Vice President of Corporate Development at Vericel Corporation and was a key member of the executive team that successfully restructured Vericel enabling it to become a commercial leader in the fields of advanced Cell Therapy and specialty Biologics.

In addition to Mr. Michel's appointment as CEO, John Purpura, was appointed as Chief Operating Officer, effective October 1, 2020. Mr. Purpura's leadership and operational excellence in areas of regulatory affairs, manufacturing and distribution have been a critical component of preparing the Company for its planned New Drug Application (NDA) resubmission to the FDA in the first quarter of 2022.

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, access to monitor trial data has decreased, causing an increase in the timelines to complete the FOCUS trial. We currently expect to announce top-line data from our FOCUS trial in early-2021 and submit an NDA to the FDA in the first quarter of 2022.

The extent to which the COVID-19 pandemic continues to 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 the EU commercial 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 potentially 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.

The COVID-19 pandemic has delayed and could further adversely affect our ability to obtain regulatory approval and commercialize our products according to current timelines, 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.

At-the-Market Offering

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

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

Rosalind Master Fund L.P. and Rosalind Opportunities Fund I L.P. (together, "Rosalind") waived, solely with respect to the ATM Offering, Rosalind's right, pursuant to that certain Support and Conversion Agreement dated March 11, 2020 between Rosalind and the Company, as amended, to participate in any offer or sale of the Company's common stock by the Company occurring within a two-year period.

On August 18, 2020, the Company and the holders of a requisite number of shares of the Company's Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock and related warrants (the "Holders") entered into an Amendment to those certain Securities Purchase Agreements, dated July 11, 2020 and August 15, 2019, among the Company and the parties signatory thereto, for the purpose of clarifying that offerings of the Company's common stock in "at the market" transactions are excluded from the rights of the holders set forth therein.

FDA Conditional Acceptance of HEPZATO KIT™ tradename

On September 9, 2020, the FDA issued its conditional acceptance of the trade name HEPZATO™ KIT for the Company's melphalan hydrochloride for injection/hepatic delivery system. A request for final approval for HEPZATO™ KIT will be included when the Company submits an NDA for the treatment of mOM.

Results of Operations for the three and nine months ended September 30, 2020

Three months ended September 30, 2020 Compared with Three months ended September 30, 2019

Revenue

We had revenue of approximately $0.5 million for the three months ended September 30, 2020 compared to $0.4 million for the three months ended September 30, 2019.

Cost of Goods Sold

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

Research and Development Expenses

Research and development expenses are incurred for the development of HEPZATO and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating pre-clinical data and the cost of manufacturing HEPZATO for clinical trials and conducting clinical trials. For the three months ended September 30, 2020 and 2019, research and development expenses increased to $3.3 million from $1.8 million. In February of 2019, cash constraints resulted in certain activities related to the FOCUS trials, such as new patient enrollment, site level data entry and site monitoring, to be paused. In January of 2020, these activities resumed resulting in an increase in research and development expenses.

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 September 30, 2020 and 2019, selling, general and administrative expenses were $2.0 million and $4.0 million, respectively. The decrease is primarily related to reduced personnel expenses as a result of reduced headcount.

Other Income/Expense

Other income/expense is primarily related to income or expense associated with financial instruments. For the three months ended September 30, 2020 and 2019, other income/expense was a negligible expense and $1.9 million of expense, respectively. The prior year period included a $1.7 million loss on the issuance of a financial instrument and $0.7 million of interest expense, partially offset by a $0.4 million gain in the fair value of a warrant liability. The decrease in the note principal balance from $10.5 million at June 30, 2019 to $2.0 million at September 30, 2019 and September 30, 2020 is the primary reason for the decrease in interest expense.

Net Loss

Our net loss for the three months ended September 30, 2020 was $5.0 million, a decrease of $2.5 million compared to net loss of $7.5 million for the three months ended September 30, 2019. The decrease in net loss is primarily due to the $1.9 million decrease in other income/expense and a $0.5 million decrease in operating expenses.

Nine months ended September 30, 2020 Compared with Nine months ended September 30, 2019

Revenue

We had revenue of approximately $1.1 million for the nine months ended September 30, 2020 compared to $1.1 million for the nine months ended September 30, 2019.

Cost of Goods Sold

For the nine months ended September 30, 2020, we recorded cost of goods sold of approximately $0.4 million compared to $0.4 million for the nine months ended September 30, 2019.

Research and Development Expenses

Research and development expenses are incurred for the development of HEPZATO and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating clinical data and the cost of manufacturing HEPZATO for clinical trials and conducting clinical trials. For the nine months ended September 30, 2020 and 2019, research and development expenses increased to $8.5 million from $6.8 million. In February of 2019, cash constraints resulted in certain activities related to the FOCUS trials, such as new patient enrollment, site level data entry and site monitoring, to be paused. In January of 2020, these activities resumed resulting in an increase in research and development expenses.

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 nine months ended September 30, 2020 and 2019, selling, general and administrative expenses were $6.6 million and $9.2 million, respectively. The decrease is primarily related to reduced personnel expenses as a result of reduced headcount.

Other Income/Expense

Other income/expense is primarily related income or expense associated with financial instruments. For the nine months ended September 30, 2020 and 2019, other income/expense was $2.8 million of expense and $6.0 million of expense, respectively. The current year period included a $2.8 million loss in the fair value of a warrant liability and $0.2 million of interest expense, partially offset by $0.2 million of other income. The prior year period included $4.7 million of interest expense and a $1.7 million loss on the issuance of a financial instrument, partially offset by a $0.4 million gain in the fair value of a warrant liability. The decrease in the note principal balance from $10.5 million at June 30, 2019 to $2.0 million at September 30, 2019 and 2020 is the primary reason for the decrease in interest expense.

Net Loss

Our net loss for the nine months ended September 30, 2020 was $17.1 million, a decrease of $4.3 million, compared to the net loss of $21.4 million for the nine months ended September 30, 2019. The decrease in net loss is primarily due to the $3.2 million decrease in other income/expense and a $1.0 million decrease in operating expenses.

Liquidity and Capital Resources

In May 2020, we consummated an underwritten public offering resulting in gross proceeds of approximately $22.0 million. In August 2020, we launched an at-the market offering of our common stock at an aggregate offering price of up to $10 million. We expect that the ongoing ATM Offering (see Note 9), and our existing cash resources will be sufficient to fund our expected operations through the second quarter of 2021, however since the proceeds from the ATM Offering are contingent on a variety of factors, including price and volume, we may choose or need to raise capital through other means prior to that. Beyond the second quarter we will need to raise additional capital 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 September 30, 2020, we had cash, cash equivalents and restricted cash totaling $11.1 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $15.5 million at September 30, 2019. During the three and nine months ended September 30, 2020 and 2019, we used $18.3 million and $18.3 million, respectively, of cash in our operating activities.

These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the financial statements included elsewhere in this Quarterly Report on Form 10-Q are issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities to support our future operations.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we anticipate that our losses will continue for the foreseeable future. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our future clinical and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

Off-Balance Sheet Arrangements

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 nine months ended September 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 recognize 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 nine months ended September 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 September 30, 2020. Management expects that the warrants outstanding at September 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, and December 31, 2019 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 Chief Executive Officer and Interim Principal Accounting Officer, evaluated the effectiveness of the design and operation of the Company’s disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act). Based on that evaluation, our Chief Executive Officer and Interim Principal Accounting Officer concluded that our disclosure controls and procedures as of September 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 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 September 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 (effective June 1, 2020) of Jennifer Simpson, the Company's former President and CEO, and Barbra Keck, the Company's former CFO (the "Claimants"), it became evident that there was a dispute regarding the Company's compensation obligations. In a letter dated, June 29, 2020, an attorney representing the Claimants made certain claims and threatened litigation against the Company. On or about July 27, 2020, the Claimants filed a statement of claim with the American Arbitration Association against the Company. The Claimants seek payment of certain purported unpaid compensation amounts claimed to be due to them, in an approximate amount of $1.14 million in the aggregate, as well as unspecified statutory damages under New York Labor Law, attorneys' fees and costs, and statutory interest. The arbitrator has scheduled hearings to take place during the week of May 17, 2021. However, the Claimants and the Company have recently agreed to participate in non-binding mediation of their dispute before a neutral mediator, which will result in the arbitration proceedings being placed in abeyance pending the outcome of the mediation process. At this time, the Company is unable to predict the timing for the mediation process, nor whether mediation will result in an amicable resolution of its dispute with the Claimants. 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

None.

Item 3.Defaults upon Senior Securities

None.

Item 4.Mine Safety Disclosures

Not Applicable.

Item 5.Other Information

On November 11, 2020, the Company issued a press release reporting its financial results for the fiscal quarter ended September 30, 2020, a copy of which is furnished as Exhibit 99.4 to this Quarterly Report on Form 10-Q.

Item 6.Exhibits

Exhibit No.	Description
1.1	Controlled Equity Offering SM Sales Agreement, dated August 18, 2020, between Delcath Systems, Inc., and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 of the Company's Form 8-K filed on August 18, 2020)***
10.1	Employment Agreement dated August 31, 2020, between Delcath Systems, Inc., and Gerard Michel. (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on October 1, 2020)***#
10.2	Inducement Award Stock Option Award Agreement dated October 1, 2020, between Delcath Systems, Inc., and Gerard Michel. (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on October 1, 2020)***#
10.3	Employee Confidentiality, Invention Assignment and Restrictive Covenants Agreement, dated August 31, 2020, between Delcath Systems, Inc., and Gerard Michel. (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on October 1, 2020)***#
10.4	Second Amendment to Sublease, dated September 22, 2020, between Delcath Systems, Inc., and Kasowitz Benson Torres LLP.*
31.1	Certification by Chief Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification by Interim Principal Accounting Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification by Interim Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
99.1	Limited Waiver dated July 17, 2020, between Delcath Systems, Inc. and ROTH Capital Partners, LLC. (incorporated by reference to Exhibit 99.1 of the Company's Form 8-K filed on August 18, 2020)***
99.2	Limited Waiver, dated July 10, 2020, between Delcath Systems, Inc. and Rosalind Master Fund L.P. and Rosalind Opportunities Fund I L.P. (incorporated by reference to Exhibit 99.2 of the Company's Form 8-K filed on August 18, 2020)***
99.3	Amendment to Securities Purchase Agreements, dated as of August 18, 2020, among Delcath Systems, Inc., and the other parties thereto. (incorporated by reference to Exhibit 99.3 of the Company's Form 8-K filed on August 18, 2020)***
99.4	Third Quarter 2020 Earnings Press Release**
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.

\# Indicates management contract or compensatory plan or arrangement required to be identified pursuant to Item 6 of this Quarterly Report on Form 10-Q

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.

November 12, 2020	DELCATH SYSTEMS, INC.
	/s/ Gerard Michel
	Gerard Michel Chief Executive Officer
November 12, 2020	/s/ Christine Padula
	Christine Padula Interim Principal Accounting Officer

Exhibit 10.4

Execution Version

SECOND AMENDMENT TO SUBLEASE

This **SECOND AMENDMENT TO SUBLEASE** (this **"Second Amendment")** is entered into this 22nd day of September 2020, by and between **KASOWITZ BENSON TORRES LLP,** a New York limited liability partnership, formerly known as Kasowitz, Benson, Torres & Friedman LLP **("Sublandlord"),** and **DELCATH SYSTEMS INC.,** a Delaware limited liability company **("Subtenant").**

WHEREAS, Sublandlord and Subtenant have entered into that certain Sublease, dated as of March 23, 2016 (the **"Original Sublease"),** as amended by that certain First Amendment to Sublease, dated September 24, 2018 (the **"First Amendment";** the Original Sublease together with the First Amendment, as amended by this Second Amendment, is referred to herein as the **"Sublease"),** pursuant to which Sublandlord has subleased to Subtenant certain premises consisting of approximately 6,877 square feet of rentable area comprising a portion of the 22nd floor (the **"Premises")** of the building located at 1633 Broadway, New York, New York 10019 (the **"Building");**

WHEREAS, pursuant to the First Amendment, Sublandlord and Subtenant amended the Original Sublease to, among other things, extend the term of the Sublease to February 28, 2021 (the **"Extended Expiration Date"),** on the terms and conditions hereinafter set forth; and

WHEREAS, Sublandlord and Subtenant desire to further amend the Sublease to, among other things, extend the term of the Sublease to February 28, 2023 (the **"Second Extended Expiration Date"),** on the terms and conditions hereinafter set forth.

NOW THEREFORE, in consideration of the foregoing premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublandlord and Subtenant, intending to be legally bound, hereby agree as follows:

1. Incorporation of Recitals. The foregoing recitals are hereby incorporated in this Second Amendment and made a part hereof by this reference.

2. Definitions. All capitalized terms used herein shall have the meanings ascribed to them in the Original Sublease, unless otherwise defined herein.

3. Term. The Term is hereby extended to, and shall expire on, February 28, 2023, unless extended or earlier terminated in accordance with the terms of the Sublease. Accordingly, the Expiration Date under the Sublease shall be deemed to be February 28, 2023. Notwithstanding anything contained herein or in the Sublease to the contrary, the Renewal Option shall remain in full force and effect, except that all references to the "Initial Expiration Date" therein shall be deemed to mean the "Second Extended Expiration Date".

4. Fixed Rent. Subtenant shall pay to Sublandlord Fixed Rent for the Premises during the period commencing on March 1, 2021 and expiring on the Expiration Date as follows:

Period	Fixed Rent per rsf	Monthly Fixed Rent	Annual Fixed Rent
03/01/21 – 02/28/23	$59.00	$33,811.92	$405,743.00

The Fixed Rent payable by Subtenant pursuant to the terms of this Section 4 shall be paid by Subtenant in accordance with the terms and provisions of the Original Sublease, as modified by this Second Amendment.

5. Notice. Paragraph 14(a) of the Original Sublease is hereby amended by deleting Sublandlord's addresses for notices therein and inserting the following in lieu thereof:

"If to Sublandlord (in two (2) separate envelopes):

Kasowitz Benson Torres LLP 1633 Broadway
New York, New York 10019
Attention: Alan Capilupi

with a copy to:

Kasowitz Benson Torres LLP 1633 Broadway
New York, New York 10019 Attention: Mitchell R. Schrage, Esq."

6. Brokers. Subtenant warrants and represents that Subtenant has had no dealings with any real estate broker, agent or finder in connection with this Second Amendment except for Savills, Inc. **("Tenant's Broker")** and Douglas Elliman Commercial, LLC **("Landlord's Broker",** and together with Tenant's Broker, collectively, the **"Brokers"),** and Subtenant agrees to indemnify and to hold Sublandlord harmless from any loss, claim or damage Sublandlord may sustain or incur arising out of any claim by any other broker, agent or finder claiming to have dealt with Subtenant for fees or commissions in connection with this Second Amendment. Sublandlord warrants and represents that Sublandlord has had no dealings with any real estate broker, agent or finder in connection with this Second Amendment except for the Brokers, and Sublandlord agrees to indemnify and hold Subtenant harmless from any loss, claim or damage Subtenant may sustain or incur arising out of any claim by any other broker, agent or finder for fees or commissions in connection with this Second Amendment. Sublandlord shall pay the Brokers a commission in connection with this Second Amendment pursuant to separate agreement.

7. Ratification. Except as expressly amended by this Second Amendment, all other terms, conditions and provisions of the Sublease are hereby ratified and confirmed and shall continue in full force and effect.

8. Representations. Subtenant hereby represents and warrants to Sublandlord that Subtenant has full power and authority to execute and perform this Second Amendment, and has taken all action necessary to authorize the execution and performance of this Second Amendment. Sublandlord hereby represents and warrants to Subtenant that Sublandlord has full power and authority to execute and perform this Second Amendment, and has taken all action necessary to authorize the execution and performance of this Second Amendment.

9. Consent of Overlandlord. Sublandlord shall use its reasonable efforts to obtain from Overlandlord written consent hereto (an **"Amendment Consent").** This Second Amendment shall have no effect unless and until Overlandlord shall have delivered an executed Amendment Consent in accordance with the terms of the Overlease and any conditions precedent with respect thereto have been satisfied or waived. If Overlandlord refuses to consent to this Second Amendment, this Second Amendment shall be deemed null and void and of no effect.

10. Miscellaneous. This Second Amendment (i) shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns (subject to the restrictions on assignment set forth in the Original Sublease), (ii) shall be governed by and construed in accordance with the laws of the State of New York (without regard to provisions regarding conflict of laws), and (iii) may be executed in multiple counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. Facsimile or .pdf signatures shall be deemed to be and shall have the same force and effect as original signatures. This Second Amendment contains and embodies the entire agreement of the parties hereto with respect to the matters set forth herein, and supersedes and revokes any and all negotiations, arrangements, letters of intent, representations, inducements or other agreements, oral or in writing with respect to such matters. No representations, inducements or agreements, oral or in writing, between the parties with respect to such matters, unless contained in this Second Amendment, shall be of any force or effect.

[SIGNATURE PAGE TO FOLLOW)

IN **WITNESS WHEREOF,** Sublandlord and Subtenant have executed this Second Amendment to Sublease as of the day and year first above written.

SUBLANDLORD:

KASOWITZ BENSON TORRES LLP,
a New York limited liability partnership

By: /s/ Mitchell R. Schrage
Name: Mitchell R. Schrage
Title: Partner

[*signatures continue on next page]*

TENANT:

DELCATH SYSTEMS, INC.,

By: /s/ John Purpura
Name: John Purpura
Title: Interim CEO, EVP, Global Head of Operations

[Signature Page - Second Amendment to Sublease]

DELCATH SYSTEMS, INC.

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

I, Gerard Michel, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 12, 2020

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer

Exhibit 31.2

DELCATH SYSTEMS, INC.

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

I, Christine Padula, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 12, 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 September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Gerard Michel, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

November 12, 2020

/s/ Gerard Michel
Gerard Michel
Chief Executive Officer

Exhibit 32.2

DELCATH SYSTEMS, INC.

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

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

November 12, 2020

/s/ Christine Padula
Christine Padula
Interim Principal Accounting Officer

Exhibit 99.4

Delcath Systems, Inc. Announces Third Quarter 2020 Results

Conference Call Today at 8:30am Eastern Time

NEW YORK, November 11, 2020 -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today reported business highlights and financial results for the third quarter ended September 30, 2020.

Recent Business Highlights

During and since the third quarter of 2020, the company:

- Strengthened the executive team with the appointment of Gerard Michel as Chief Executive Officer.
- Announced the conditional acceptance by the FDA of the trade name HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system) for Melphalan/HDS.
- Announced the treatment of the final patient in the FOCUS trial; to date, 91 patients have been treated with a total of 356 treatments.
- Confirmed the expected announcement of topline data in early 2021 and updated the expected NDA submission timing to the first quarter of 2022.
- Provided details that for analytical purposes, the FOCUS trial should demonstrate an overall response rate of at least 21% to show superiority over a meta-analysis of immuno-oncology trials in metastatic ocular melanoma (mOM).
- Held a key opinion leader call with Dr. Mark Burgmans, Head of Interventional Radiology at the Leiden University Medical Center, to discuss the results of a prospective study, published in August 2020 in the Annals of Surgical Oncology, which reported an overall response rate of 72% in patients with metastatic ocular melanoma with metastases confined to the liver. As stated in the publication, treating the patients early in the disease cycle and the exclusion of patients with extra-hepatic disease likely contributed to the favorable outcome observed in this study. Observed safety events were primarily hematological in nature and deemed to be expected and manageable.

“I have joined the Delcath team at an exciting moment in the company’s history as we approach the announcement of the FOCUS trial’s topline results and the evidence continues to build that HEPZATO has the potential to be an important treatment for metastatic ocular melanoma,” said Gerard Michel, CEO of Delcath. “2021 will represent an inflection point for the company as we execute on four key priorities including compiling the HEPZATO KIT NDA, preparing for commercialization, raising awareness with investors and expanding the development of HEPZATO into additional areas of high unmet need.”

Third Quarter 2020 Financial Results:

Income Statement Highlights.

Product revenue for the three months ended September 30, 2020 was approximately $340 thousand, compared to $216 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $2.0 million compared to $4.0 million in the prior year quarter. Research and development expenses for the third quarter were $3.3 million compared to $1.8 million in the prior year quarter. Total operating expenses for the third quarter were $5.3 million compared with $5.8 million in the prior year quarter.

We recorded a net loss for the three months ended September 30, 2020, of $5.0 million, compared to a net loss of $7.5 million for the same period in 2019.

Balance Sheet Highlights.

At September 30, 2020, we had cash, cash equivalents and restricted cash totaling $11.1 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $15.5 million at September 30, 2019. During the three months ended September 30, 2020 and September 30, 2019, we used $5.2 million and $12.4 million, respectively, of cash in our operating activities.

Conference Call Information

To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call.

Date: November 11, 2020
Time: 8:30 AM Eastern Time
Toll Free: 877-407-8035
International: 201-689-8035

The call will also be available over the Internet and accessible at: https://www.webcaster4.com/Webcast/Page/2475/38241

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

Safe Harbor / Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the timing and results of the Company's clinical trials, including without limitation the mOM and ICC clinical trial programs, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial and the impact of the COVID-19 pandemic on the completion of our clinical trials; the impact of the presentations at major medical conferences and future clinical results consistent with the data presented; approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure; the impact, if any, of ZE reimbursement on potential CHEMOSAT product use and sales in Germany; clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK; the Company's ability to successfully commercialize the HEPZATO KIT/CHEMOSAT system and the potential of the HEPZATO KIT/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver; our ability to obtain reimbursement for the CHEMOSAT system in various markets; approval of the current or future HEPZATO KIT/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets; actions by the FDA or foreign regulatory agencies; the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same; uncertainties relating to the timing and results of research and development projects; and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Contact:

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Hayden IR

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

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 10,899	$ 10,002
Restricted cash	181	181
Accounts receivables, net	103	21
Inventories	839	654
Prepaid expenses and other current assets	1,860	1,759
Total current assets	13,882	12,617
Property, plant and equipment, net	1,318	735
Deferred offering costs	268	—
Right-of-use assets	1,097	860
Total assets	$ 16,565	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,502	$ 4,533
Accrued expenses	6,085	6,947
Deferred revenue, current	501	482
Lease liabilities, current	556	664
Convertible notes payable, current	2,000	—
Warrant liability	—	3,368
Total current liabilities	10,644	15,994
Deferred revenue, non-current	2,103	2,378
Lease liabilities, non-current	542	197
Convertible notes payable, non-current	—	2,000
Total liabilities	13,289	20,569
Commitments and contingencies (Note 13)	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 21,473 and 41,517 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 4,035,558 and 67,091 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively*	40	1
Additional paid-in capital	391,545	364,785
Accumulated deficit	(388,298)	(371,171)
Accumulated other comprehensive income	(11)	28
Total stockholders' equity (deficit)	3,276	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 16,565	$ 14,212

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

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

	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Product revenue	$ 340	$ 216	$ 778	$ 528
Other revenue	126	164	361	535
Cost of goods sold	(188)	(172)	(434)	(440)
Gross profit	278	208	705	623
Operating expenses:				
Research and development expenses	3,260	1,778	8,457	6,789
Selling, general and administrative expenses	1,998	4,002	6,571	9,204
Total operating expenses	5,258	5,780	15,028	15,993
Operating loss	(4,980)	(5,572)	(14,323)	(15,370)
Change in fair value of the warrant liability, net	—	434	(2,832)	451
Loss on issuance of financial instrument	—	(1,714)	—	(1,721)
Interest expense	(44)	(671)	(154)	(4,735)
Other income	33	4	182	4
Net loss	(4,991)	(7,519)	(17,127)	(21,371)
Deemed dividend for triggering of warrant down round feature	—	—	(55)	—
Net loss attributable to common stockholders	$ (4,991)	$ (7,519)	$ (17,182)	$ (21,371)
Net loss	$ (4,991)	$ (7,519)	$ (17,127)	$ (21,371)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(103)	89	(39)	39
Total other comprehensive loss	$ (5,094)	$ (7,430)	$ (17,166)	$ (21,332)
Common share data:				
Basic loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Diluted loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Weighted average number of basic shares outstanding*	4,288,593	101,862	2,217,611	102,956
Weighted average number of diluted shares outstanding*	4,288,593	101,862	2,217,611	102,956

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