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

FORM 10-Q

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

For the quarterly period ended March 31, 2019

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	OTC Pink

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 July 17, 2019, 18,277,807 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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

	March 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 264	$ 2,516
Restricted cash	1,062	1,062
Accounts receivables, net	62	585
Inventories	775	858
Prepaid expenses and other current assets	1,003	898
Total current assets	3,166	5,919
Property, plant and equipment, net	861	925
Right-of-use assets	2,137	—
Total assets	$ 6,164	$ 6,844
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 10,268	$ 7,715
Accrued expenses	8,360	7,964
Notes payable, net of debt discount	5,390	—
Convertible notes payable, net of debt discount	367	2,038
Lease liabilities, current portion	1,024	—
Warrant liability	26	33
Total current liabilities	25,435	17,750
Deferred revenue	3,223	3,405
Lease liabilities, long-term portion	1,117	—
Other non-current liabilities	166	628
Total liabilities	29,941	21,783
Commitments and Contingencies	—	—
Stockholders' deficit		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares and 101 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 14,434,454 and 10,299,954 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively*	144	103
Additional paid-in capital	327,969	328,962
Accumulated deficit	(351,947)	(344,054)
Accumulated other comprehensive income	57	50
Total stockholders' deficit	(23,777)	(14,939)
Total liabilities and stockholders' deficit	$ 6,164	$ 6,844

*reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three months ended March 31, 2019	2018
Product revenue	$ 90	$ 702
Other revenue	180	—
Cost of goods sold	(96)	(147)
Gross profit	174	555
Operating expenses:		
Selling, general and administrative	2,549	2,366
Research and development	3,298	5,692
Total operating expenses	5,847	8,058
Operating loss	(5,673)	(7,503)
Change in fair value of the warrant liability, net	7	14,697
Interest expense	(2,229)	(2)
Other income (expense)	2	(5)
Net (loss) income	$ (7,893)	$ 7,187
Other comprehensive (loss) income:		
Foreign currency translation adjustments	57	(34)
Comprehensive (loss) income	$ (7,836)	$ 7,153
Common share data:		
Basic (loss) income per common share*	$ (0.11)	$ 10.91
Diluted (loss) income per common share*	$ (0.11)	$ 10.91
Weighted average number of basic shares outstanding*	73,558,713	658,893
Weighted average number of diluted shares outstanding*	73,558,713	658,893

*reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Common Stock Issued $0.01 Par Value		Preferred Stock Issued $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at January 1, 2019	10,299,954	$ 103	101	$ —	$ 328,962	$ (344,054)	$ 50	$ (14,939)
Compensation expense for issuance of stock options	—	—	—	—	54	—	—	54
Compensation expense for issuance of restricted stock	15,000	—	—	—	4	—	—	4
Issuance of Series D Preferred Stock	—	—	15	—	150	—	—	150
Retirement of Series D Preferred Stock	—	—	(116)	—	(1,160)	—	—	(1,160)
Exercise of Pre-Funded Series D Warrants	4,119,500	41	—	—	(41)	—	—	—
Net loss	—	—	—	—	—	(7,893)	—	(7,893)
Total comprehensive loss	—	—	—	—	—	—	7	7
Balance at March 31, 2019	14,434,454	$ 144	—	$ —	$ 327,969	$ (351,947)	$ 57	$ (23,777)

	Common Stock Issued $0.01 Par Value		Treasury Stock					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2018	228,140	$ 2	(1)	$ (51)	$ 325,517	$ (324,832)	$ 42	$ 678
Compensation expense for issuance of stock options	—	—	—	—	7	—	—	7
Compensation expense for issuance of restricted stock	—	—	—	—	14	—	—	14
Sale of common stock, net of expenses	668,855	7	—	—	4,245	—	—	4,252
Fair value of warrants issued	—	—	—	—	(18,306)	—	—	(18,306)
Net income	—	—	—	—	—	7,187	—	7,187
Total comprehensive loss	—	—	—	—	—	—	(34)	(34)
Balance at March 31, 2018	896,995	$ 9	(1)	$ (51)	$ 311,477	$ (317,645)	$ 8	$ (6,202)

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three months ended March 31, 2019	2018
Cash flows from operating activities:		
Net (loss) income	$ (7,893)	$ 7,187
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	54	7
Restricted stock compensation expense	4	14
Depreciation expense	65	120
Warrant liability fair value adjustment	(7)	(14,697)
Non-cash interest income	—	(4)
Interest expense accrued related to convertible notes	51	
Debt discount amortization	2,160	—
Changes in assets and liabilities:		
Prepaid expenses and other assets	(108)	152
Accounts receivable	523	(24)
Inventories	61	24
Accounts payable and accrued expenses	2,902	828
Deferred revenue	(120)	—
Other non-current liabilities	(462)	(50)
Net cash used in operating activities	(2,770)	(6,443)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2)	(6)
Net cash used in investing activities	(2)	(6)
Cash flows from financing activities:		
Net proceeds from the issuance of debt	400	—
Net proceeds from sale of Series D Preferred Stock	150	—
Net proceeds from sale of common stock and warrants	—	4,253
Net cash provided by financing activities	550	4,253
Foreign currency effects on cash, cash equivalents and restricted cash	(30)	(12)
Net decrease in cash, cash equivalents and restricted cash	(2,252)	(2,208)
Cash, cash equivalents and restricted cash:		
Beginning of period	3,578	5,324
End of period	$ 1,326	$ 3,116
Supplemental non-cash financing activities:		
Fair value of warrants issued	$ —	$ 18,306

See accompanying Notes to Condensed Consolidated Financial Statements.

(1) General

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. ("Delcath" or the "Company") as of and for the three months ended March 31, 2019 and 2018 should be read in conjunction with the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 ("Annual Report"), which has been filed with the Securities Exchange Commission ("SEC") on June 14, 2019 and can also be found on the Company's website (www.delcath.com). In these notes the terms "us", "we" or "our" refer to Delcath and its consolidated subsidiaries.

Description of Business

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

Our primary research focus is on ocular melanoma liver metastases ("mOM") and intrahepatic cholangiocarcinoma ("ICC"), a type of primary liver cancer, and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Our clinical development program ("CDP") for Melphalan/HDS is comprised of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the "ALIGN Trial"). Our CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials ("IITs").

Liquidity and Operating Matters

The accompanying 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 raises 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.

The preparation of interim financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements, in the opinion of management, 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 three months ended March 31, 2019 and 2018; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 *Summary of Significant Accounting Policies* to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K filed for the period ended December 31, 2018.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) effective January 1, 2019, electing the practical expedients and applying the transition provisions as of the effective date. Reporting periods beginning on or after January 1, 2019 are presented under Topic 842, while prior period amounts, as reported under previous GAAP, were not adjusted. The adoption of Topic 842 on January 1, 2019 did not have a significant impact on the Company's consolidated results of operations or cash flows.

(2) Restricted Cash

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

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

(in thousands)	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 264	$ 2,516
Letters of credit	1,012	1,012
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 1,326	$ 3,578

(3) Inventories

Inventories consist of the following:

(in thousands)	March 31, 2019	December 31, 2018
Raw materials	$ 341	$ 358
Work-in-process	434	500
Total inventories	$ 775	$ 858

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	March 31, 2019	December 31, 2018
Income tax and VAT receivable	566	579
Insurance premiums	192	140
Security deposit	50	51
Financing costs	64	—
Other[1]	131	128
Total prepaid expenses and other current assets	$ 1,003	$ 898

[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 March 31, 2019 and December 31, 2018.

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	March 31, 2019	December 31, 2018	Estimated Useful Life
Buildings and land	$ 589	$ 589	30 years - Buildings
Enterprise hardware and software	1,741	1,742	3 years
Leaseholds	1,696	1,701	Lesser of lease term or estimated useful life
Equipment	1,002	1,002	7 years
Furniture	198	198	5 years
Property, plant and equipment, gross	5,226	5,232	
Accumulated depreciation	(4,365)	(4,307)	
Property, plant and equipment, net	$ 861	$ 925	

Depreciation expense for the three months ended March 31, 2019 was approximately $0.1 million as compared to approximately $0.1 million, for the same period in 2018.

(6) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	March 31, 2019	December 31, 2018
Compensation, excluding taxes	$ 3,122	$ 1,785
Clinical trial expenses	4,151	4,530
Other[1]	1,087	1,649
Total accrued expenses	$ 8,360	$ 7,964

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at March 31, 2019 and December 31, 2018.

(7) Leases

The Company recognizes right-of-use (“ROU”) assets and lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve months. The Company leases its facilities under non-cancellable operating and financing leases.

The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the ROU asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company’s leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments.

The following table summarizes the Company's operating and financing leases as of and for the three months ended March 31, 2019:

(in thousands)	U.S.	Ireland	Total
Lease cost			
Operating lease cost	$ 242	$ 56	$ 298
Financing lease cost	8	—	8
Sublease income	(107)	(47)	(154)
Total	$ 143	$ 9	152
Other information			
Operating cash flows out from operating leases	(262)	(56)	(318)
Operating cash flows in from operating leases	107	47	154
Operating cash flows from financing leases	(12)	—	(12)
Right-of-use assets exchanged for new operating lease liabilities	874	—	874
Weighted average remaining lease term	1.9	2.4	
Weighted average discount rate - operating leases	8%	8%	

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

(in thousands)	U.S.	Ireland	Total
Nine months ended December 31, 2019	$ 710	$ 168	$ 878
Year ended December 31, 2020	936	225	1,161
Year ended December 31, 2021	190	131	321
Total	1,836	524	2,360
Less present value discount	(172)	(47)	(219)
Operating lease liabilities included in the condensed consolidated balance sheets at March 31, 2019	$ 1,664	$ 477	$ 2,141

(8) Outstanding Debt

On June 4, 2018, July 21, 2018, August 29, 2018, and September 21, 2018, the Company issued 8% senior secured convertible notes (collectively, "the Notes") to investors with aggregate principal amount of $9.4 million and maturity dates between December 2018 and March 2021. The Notes are secured pursuant to a Security Agreement which creates a first priority security interest in all of the personal property (other than Excluded Collateral (as defined in the Security Agreement) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future.

In April 2019, the Company received notices of default from the investors in the Notes.

Amendment to June 2018, July 2018 and August 2018 Notes

In March 2019, the Company amended the June 2018, July 2018 and August 2018 Notes to make them non-convertible. There was no impact to the financial statements.

Issuance of March 2019 Notes

In March 2019, the Company exchanged all of its Series D Preferred Stock (with a stated value of $1,160,000) and received $400,000 in proceeds and issued a senior secured promissory note with a principal amount of $1,560,000. The note is due on April 1, 2020, bears interest at 8% per annum and is nonconvertible. The principal was recognized in notes payable on the Condensed Consolidated Balance Sheet.

The following tables provide a summary of the Notes by their maturity dates (absent provisions of default) at March 31, 2019 and December 31, 2018:

(in millions)	Interest rate	Conversion price	Principal	Unamortized Discount	Carrying value
Short term convertible notes payable					
March 21, 2019	8.0%	$ 1.75	$ 0.4	$ (0.1)	$ 0.3
March 21, 2020	8.0%	$ 1.75	0.1	—	0.1
			0.5	(0.1)	0.4
Short term notes payable					
December 4, 2018	8.0%	—	1.7	—	1.7
March 1, 2019	8.0%	—	0.6	—	0.6
December 4, 2019	8.0%	—	0.9	(0.2)	0.7
March 1, 2020	8.0%	—	0.8	—	0.8
April 1, 2020	8.0%	—	1.6	—	1.6
			5.6	(0.2)	5.4
Balance at March 31, 2019			**$ 6.1**	**$ (0.3)**	**$ 5.8**

(in millions)	Interest rate	Conversion price	Principal	Unamortized Discount	Carrying value
December 4, 2018	8.0%	$ 1.75	$ 1.7	$ —	$ 1.7
March 1, 2019	8.0%	$ 1.75	0.6	(0.5)	0.1
March 21, 2019	8.0%	$ 1.75	0.4	(0.2)	0.2
December 4, 2019	8.0%	$ 1.75	0.9	(0.9)	—
March 1, 2020	8.0%	$ 1.75	0.8	(0.8)	—
March 21, 2020	8.0%	$ 1.75	0.1	(0.1)	—
Balance at December 31, 2018			**$ 4.5**	**$ (2.5)**	**$ 2.0**

(9) Stockholders' Equity

Preferred Stock Issuances

Series D Preferred Stock

On November 5, 2018, the Company's Board authorized the establishment of a new series of preferred stock designated as Series D Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock which was filed with the State of Delaware on November 5, 2018. On March 29, 2019, the Company exchanged all of its Series D Preferred Stock (with a stated value of $1,160,000) and received $400,000 in proceeds and issued a senior secured promissory note to an investor with a principal amount of $1,560,000.

Common Stock Issuances

During the three months ended March 31, 2019 the Company issued 4.1 million shares pursuant to the exercise of Pre-Funded Series D Warrants.

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 authorized for issuance under the Plan is 1,500,000. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant. As of March 31, 2019, the Plan had approximately 333,333 shares available for grant.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	—			
Granted	1,250,000	0.28		
Exercised	—			
Cancelled/Forfeited	(83,333)	0.28		
Outstanding at March 31, 2019	1,166,667	$ 0.28	9.08	$ —
Exercisable at March 31, 2019	112,498	$ 0.28	8.43	$ —

The following weighted average assumptions were used to compute the fair value of stock options granted during the three months ended March 31, 2019:

	Three months ended March 31, 2019
Dividend yield	N/A
Expected volatility	147.6%
Weighted average risk-free interest rate	2.6%
Weighted average expected life (in years)	5.5
Weighted average grant date fair value	$ 0.259

For the three months ended March 31, 2019, the Company recognized compensation expense of approximately $54,000 relating to stock options granted to employees. For the same period in 2018, the Company recognized compensation expense of approximately $7,000.

For the three months ended March 31, 2019 the Company recognized compensation expense of approximately $4,000 relating to restricted stock granted to consultants. For the same period in 2018, the Company recognized compensation expense of approximately $14,000 related to restricted stock granted to employees.

Warrants

The following is a summary of warrant activity for the three months ended March 31, 2019:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2018	65,685,269	$0.01 - $10.00	$ 0.22	5.75
Exercised	(4,119,500)		0.01	
Expired	—		—	
Outstanding at March 31, 2019	61,565,769	$0.01 - $10.00	$ 0.23	5.49

(10) Fair Value Measurements

The table below presents the activity within Level 3 of the fair value hierarchy for the three months ended March 31, 2019:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2018	$ 33
Total change in the liability included in earnings	(7)
Balance at March 31, 2019	$ 26

Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2019 and December 31, 2018 was determined by using option pricing models with the following assumptions:

	March 31, 2019	December 31, 2018
Expected life (in years)	4.75	1.13 - 5.11
Expected volatility	146.4%	145.7% - 265.3%
Risk-free interest rates	2.2%	2.5% - 2.6%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2019, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
(in thousands)	Level 1		Level 2		Level 3		Total	
	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018
Liabilities								
Derivative instrument liabilities	$ —	$ —	$ —	$ —	$ 26	$ 33	$ 26	$ 33

For the periods ended March 31, 2019 and December 31, 2018, there were no transfers in or out of Level 1, 2 or 3 inputs.

(11) Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities except for those shares that are issuable for little or no cash consideration. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

	March 31,	
(in thousands, except share data)	2019	2018
Net loss - basic	$ (7,893)	$ 7,187
Adjustment for gain on warrant income	—	(14,697)
Net loss - diluted	$ (7,893)	$ (7,510)
Weighted average shares outstanding - basic*	73,558,713	658,893
Weighted average shares outstanding - diluted*	73,558,713	658,893
Net loss per share - basic*	$ (0.11)	$ 10.91
Net loss per share - diluted*	$ (0.11)	$ 10.91

*reflects a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

The following potentially dilutive securities were excluded from the computation of earnings per share as of March 31, 2019 and 2018 because their effects would be anti-dilutive:

	March 31,	
	2019	2018
Common stock warrants - equity	4,202,909	—
Common stock warrants - liability	189,029	1,014,041
Stock options	1,166,667	—
Assumed conversion of convertible notes	268,558	—
Total	5,827,163	1,014,041

(12) Taxes

As discussed in Note 14 *Income Taxes* to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K filed for the period ended December 31, 2018, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations. Additional information regarding the statutes of limitations can be found in Note 14 *Income Taxes* to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K filed for the period ended December 31, 2018.

(13) Commitment and Contingencies

As previously reported, on March 26, 2019, the Company commenced an action (the "Action") in the Commercial Division of the Supreme Court for the State of New York, County of New York, styled as Delcath Systems, Inc., v. Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd., L1 Capital Global Opportunities Master Fund and First Fire Global Opportunities Fund LLC (Index No. 651749/2019). The Action seeks expedited equitable relief in the form of reformation and a declaratory judgement to remedy a scrivener's error in the Series D Warrants issued in the Company's February 2018 public offering such that those warrants do not contain a price and quantity ratchet upon a sale of Company securities at a price lower than the offering price in the February 2018 offering. The defendant, L1 Capital Global Opportunities Master Fund, settled with the Company by exchanging its Series D Warrants for Company common stock on a one-for-one basis, which is the same ratio for which other investors in the February 2018 round exchanged their Series D Warrants in December 2018. The Company and the remaining defendants in the Action, Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd. and First Fire Global Opportunities Fund LLC, entered into a settlement agreement on April 18, 2019 pursuant to which such defendants surrendered the Series D Warrants and waived all rights granted to them by or in connection with the Series D Warrants and all rights afforded to them to participate in the Company's future common stock offerings. In consideration therefor, pursuant to the settlement agreement, (i) the Company paid one-fifth of the reasonable fees and expenses of defendants' counsel incurred in connection with the Action and negotiation of the settlement agreement, the total of which shall not exceed $50,000 (the "Settlement Fees") and (ii) subject to the Company securing and closing certain contemplated financing, the Company agreed to pay to the defendants $400,000 and the remaining Settlement Fees. On July 17, 2019, the Company paid the amount of $440,000 to the defendants pursuant to the settlement agreement from the net proceeds received by the Company in a closing of a private placement transaction discussed in Note 14 below.

On May 9, 2018, the Company received a Demand Letter from a vendor for an outstanding balance owed at that time of $2.1 million. The Company has worked with the vendor since that time to establish a payment plan for the balance owed.

(14) Subsequent Events

Debt Issuances

On April 19, 2019, April 26, 2019, May 9, 2019 and May 23, 2019, the Company borrowed an aggregate $3.3 million from two institutional investors and issued promissory notes to the investors. The promissory notes have an aggregate principal amount of $3.3 million, bear interest at the rate of 8% per annum and are due six months from the issuance of each note. The promissory

notes are nonconvertible. The notes contain standard events of default and remedies therefor. The Company's obligations under the promissory notes to the institutional investor are secured by a lien on the Company's assets.

On June 6, 2019, the Company entered into an agreement with two institutional investors, pursuant to which the investors agreed to transfer and surrender to the Company for cancellation of 3.9 million Series D Warrants and 53.4 million Pre-Funded Series D Warrants. Under the terms of the Purchase Agreement, the investors agreed to defer the payment of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants and, accordingly, the Company agreed to sell and issue to the investors 8% Senior Secured Promissory Notes in an aggregate principal amount of $2 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants.

Equity Financing

On July 11, 2019, the Company and certain accredited investors (each an "Investor" and, collectively, the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company expects to sell and issue to the Investors an aggregate of 20,000 shares of Series E Convertible Preferred Stock, par value $0.01 per share, at a price of $1,000 per share (the "Private Placement"). Pursuant to the Securities Purchase Agreement, the Company will issue to each Investor a warrant (a "Warrant") to purchase a number of shares of common stock of the Company, par value $0.01 per share ("Common Stock"), equal to the number of shares of Common Stock issuable upon conversion of the Series E Preferred Stock purchased by the Investor. Each Warrant will have an exercise price equal to $0.06, subject to adjustment in accordance with the terms of the Warrants (the "Exercise Price"), and be exercisable at any time beginning on the date that the Company effects a reverse stock split until 5:00 p.m. (NYC time) on the date that is five years following the date that the Company effects a reverse stock split. The Company expects to receive gross proceeds from the Private Placement of approximately $20.0 million, before deducting cash fees in the amount of $1.4 million payable to Roth Capital Partners, LLC ("Roth") for serving as placement agent for the Private Placement and cash fees in the amount of $552,000 payable to Roth for serving as placement agent for certain prior securities offerings by the Company, and other transaction costs, fees and expenses payable by the Company.

Warrant exercises

3.8 million Pre-Funded Series D Warrants have been exercised.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the financial condition and results of operations of Delcath Systems, Inc. ("Delcath" or the "Company") should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2018 included in the Company's 2018 Annual Report on Form 10-K to provide an understanding of its results of operations, financial condition and cash flows.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q for the period ended March 31, 2019 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 for the period ending March 31, 2019 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 Exchange Act and Section 27A of the Securities Act. 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 for the period ended March 31, 2019 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 period ended December 31, 2018 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and system;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

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

Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this report as well as Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's 2018 Annual Report on Form 10-K.

Company Overview

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System ("Melphalan/HDS") —is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our system is commercially available under the trade name Delcath Hepatic CHEMOSAT ®

Delivery System for Melphalan ("CHEMOSAT"), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our primary research focus is on ocular melanoma liver metastases ("mOM") and intrahepatic cholangiocarcinoma ("ICC"), a type of primary liver cancer, and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Our clinical development program ("CDP") for Melphalan/HDS is comprised of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in mOM, and the ALIGN Trial, a global Phase 3 clinical trial for ICC (the "ALIGN Trial"). Our CDP also includes a registry for CHEMOSAT commercial cases performed in Europe and sponsorship of select investigator-initiated trials ("IITs").

The direction and focus of our CDP for CHEMOSAT and Melphalan/HDS is informed by; prior clinical development conducted between 2004 and 2010, commercial experience with CHEMOSAT cases performed on patients in Europe, and prior regulatory engagement with the FDA. Experience gained from this research and development, early European commercial cases and United States regulatory opinion has led to the implementation of several safety improvements to our product and the associated medical procedure.

In the United States, Melphalan/HDS is considered a combination drug and device product and is regulated as a drug by the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing reimbursement coverage for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Cancers in the Liver – A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to the American Cancer Society's ("ACS") *Cancer Facts & Figures 2018* report, cancer is the second leading cause of death in the United States, with an estimated 609,640 deaths and 1.7 million new cases expected to be diagnosed in 2018. Cancer is one of the leading causes of death worldwide, accounting for approximately 9.6 million deaths and 18.1 million new cases in 2018 according to GLOBOCAN, the database of the International Association of Cancer Registries. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the United States in 2015 was $80.2 billion. The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death. Patient prognosis is generally poor once cancer has spread to the liver.

Liver Cancers—Incidence and Mortality

There are two types of liver cancers: primary liver cancer and metastatic liver disease. Primary liver cancer (hepatocellular carcinoma or "HCC", including ICC, originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver disease, also called liver metastasis, or secondary liver cancer, is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their

primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

Ocular Melanoma

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Based on third party research that we commissioned in 2018, we estimate that up to 4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, we estimate that approximately 90% of patients will develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care for patients with ocular melanoma liver metastases. Based on the research conducted in 2018, we estimate that approximately 2,000 patients with ocular melanoma liver metastases in the United States and Europe may be eligible for treatment with the Melphalan/HDS.

Intrahepatic Cholangiocarcinoma

Hepatobiliary cancers include HCC and ICC, and are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of hepatobiliary cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 42,030 new cases of these cancers are expected to be diagnosed in the United States in 2019, leading to approximately 31,780 deaths.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of hepatobiliary cases diagnosed in the United States and Europe annually. We believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. According to third party research that we commissioned in 2018 we estimate that approximately 9,300 ICC patients in the United States and Europe annually could be candidates for treatment with Melphalan/HDS, which we believe represents a significant market opportunity.

According to the ACS, the overall five-year survival rate for hepatobiliary cancers in the United States is approximately 18%. For patients diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 31%. The ACS estimates that 5-year survival for all cancers is 68%.

About CHEMOSAT and Melphalan/HDS

Our product administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with a chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion, PHP ®, (“PHP therapy”), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient’s circulatory system.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT and Melphalan/HDS is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included as part of the system, if approved. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Risks associated with the CHEMOSAT and Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT and Melphalan/HDS is associated with adverse events, some of which can be potentially life threatening.

Procedure and Product Refinements

In 2012, we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other device component product enhancements. Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS, in a commercial setting, have suggested that these product improvements and procedure refinements have improved the safety profile. Since 2017, physicians in Europe and the United States have presented and published the results of research that signaled an improved safety profile, as well as efficacy in multiple tumor types. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials in our current CDP.

Prior United States Regulatory Experience

In August 2012 we submitted a New Drug Application ("NDA") under Section 505(b)(2) of the Federal Food Drug Cosmetic Act (FFDCA) seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, subsequently amended to ocular melanoma metastatic to the liver. Data submitted to the Food and Drug Administration (FDA) included the early clinical trial versions of the system, along with early clinical procedure techniques based on research conducted between 2005 and 2010. A full discourse of this NDA submission, including the outcome of an ODAC panel on May 2, 2013 and the FDA's issuance of a Complete Response Letter, in September 2013, is provided in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Active Clinical Development Program

The focus of our CDP is to generate clinical data for the CHEMOSAT and Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT and Melphalan/HDS and to the PHP therapy have addressed the adverse event profile and procedure-related risks observed during previous Phase 2 and 3 clinical trials. Our CDP is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals in various jurisdictions, including the United States.

The FOCUS Trial - NCT02678572
On July 27, 2018, after extensive discussions with FDA, we announced an amendment to our Phase 3, randomized clinical trial in ocular melanoma liver metastases which altered the trial protocol to a non-randomized, single-arm study. Under the terms of the amendment, the trial, now titled *A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma*, will enroll a minimum of 80 patients with ocular melanoma metastatic to the liver. Under the new protocol, the primary endpoint for the amended FOCUS trial will be objective response rate ("ORR"). Secondary endpoints will include duration of response, disease control rate, overall survival and progression-free survival. Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety and other pharmacokinetic measures. Inclusion and exclusion criteria remain unchanged. Patients previously enrolled in the Melphalan/HDS arm of the trial under the previous protocol will continue to be treated and statistically evaluated as part of the amended trial.

The rarity of ocular melanoma, absence of crossover to the experimental trial arm, and the availability of PHP® Therapy in a commercial setting in Europe have all combined to impede enrollment in this trial under its previous protocol. This amendment was intended to accelerate our timeline to complete trial enrollment while providing a strong scientific case to support an application for approval. However, accrual of new patients in this trial slowed due to the cash limitations we operated under in recent months. With the new capital investment we announced on July 11, 2019 we believe we can complete patient enrollment in this trial during the second half of 2019.

The amendment invalidated the prior Special Protocol Assessment ("SPA") agreement for the prior version of the trial. Full details of the registration Phase 3 clinical trial are available at www.clinicaltrials.gov.

The FOCUS Trial is being conducted at leading cancer centers in the United States and Europe. The Moffitt Cancer Center in Tampa, Florida was activated as a participating center in January 2016 with Jonathan Zager, M.D., FACS, Professor of Surgery in the Cutaneous Oncology and Sarcoma Departments and a Senior Member at Moffitt Cancer Center, serving as the trial's lead investigator. In October 2018, we announced continued rollout of the amended protocol to participating centers in the United States, and expect approximately 30 leading cancer centers in the United States and Europe to participate in the trial.

We believe that ocular melanoma liver metastases represent a significant unmet medical need, and that pursuit of an indication in this disease state represents the fastest path to potential marketing approval of the Melphalan/HDS in the United States.

The ALIGN Trial - NCT03086993

In April 2018 we announced the initiation of a new pivotal trial of Melphalan/HDS to treat patients with ICC titled *A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma (The ALIGN Trial)*. The ALIGN trial is being conducted under a SPA announced in March of 2017. Under the terms of the SPA, the ALIGN Trial will enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint is overall survival ("OS") and secondary and exploratory endpoints include safety, progression-free survival ("PFS"), ORR and quality-of-life measures. The ALIGN Trial is designed to be cost effective and pursued in a financially prudent manner when financial resources permit. The SPA agreement for the ALIGN TRIAL indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS in ICC. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

In October 2018, we announced the enrollment of the first patient in The ALIGN Trial *at The University of Tennessee Health Science Center, Methodist University Hospital, and West Cancer Center* in Memphis, Tennessee.

Phase 2 Hepatocellular Carcinoma (HCC) & Intrahepatic Cholangiocarcinoma (ICC) Program

In 2014 we initiated a Phase 2 clinical trial program in Europe and the United States, with the goal of obtaining an efficacy and safety signal for Melphalan/HDS in the treatment of HCC and ICC. Due to differences in treatment practice patterns between Europe and the United States, we established separate European and United States trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

Protocol 201 NCT02406508 – Conducted in the United States, this trial was intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. **This trial was terminated earlier than planned and is now closed to enrollment.**

Protocol 202 NCT02415036 – Conducted in Europe, this trial was intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial will also evaluate overall response rate via mRECIST criteria, progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. **This trial was terminated earlier than planned and is now closed to enrollment.**

ICC Cohort – In 2015 we expanded *Protocol 202* to include a cohort of patients with ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. **This trial has completed enrollment and data from this study are being analyzed and will be disseminated publicly by the investigators.**

ICC Retrospective Data Collection - The original goal to obtain an efficacy signal for the Phase 2 ICC cohort has been satisfied by the result of multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These promising outcomes and observations were discussed with Key Opinion Leaders at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP therapy does "demonstrate an efficacy signal in ICC and is worthy of full clinical investigation." Data from this retrospective data collection provided important scientific support during our negotiations with the FDA for our SPA for the Pivotal ICC Trial. Data for the retrospective data collection were published in European Radiology in a paper titled "Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival". Details of the findings from this study are discussed below under "Recent Data Presentations".

With the objectives of identifying an efficacy signal worthy of further clinical investigation now met, we have terminated enrollment in our Phase 2 program and have closed the Phase 2 trials in order to focus available resources on the FOCUS Trial and the ALIGN Trial.

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy. A substantial portion of the Company's operating expenses consist of research and development expenses incurred in connection with its clinical trials. See the Company's consolidated financial statements included in Item 8 of its Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

European Investigator Initiated Trials

In addition to the clinical trials in our CDP, we are supporting data generation in other areas. We are currently conducting one IIT in colorectal carcinoma metastatic to the liver ("mCRC") at Leiden University Medical Center in the Netherlands. We continue to

evaluate other IITs as suitable opportunities present in Europe. We believe IITs will serve to build clinical experience at key cancer centers and will help support efforts to obtain full reimbursement in Europe.

European Clinical Data Generation

On April 2, 2015, we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is considered to be supportive data and, as such, cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable supportive data repository that contains real-world evidence, from a commercial setting, that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

Recent Data Presentations

In April 2019 we announced that results from a prospective Phase 2 study conducted by Leiden University Medical Center ("LUMC") in the Netherlands on the use of CHEMOSAT to treat patients with metastatic ocular melanoma with liver metastases were presented at the European Conference on Interventional Oncology annual meeting.

The LUMC study titled "Percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from ocular melanoma using the Delcath System's second-generation hemofiltration system: a prospective phase II study" was conducted by a team led and presented by Dr. Mark Burgmans. The study evaluated 35 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between February 2014 and June 2017. The 35 patients underwent a total of 72 PHP therapy treatments, and tumor response was evaluable in 32 patients. Primary endpoints were overall response, overall survival, and progression free survival. Secondary measures included safety measures and hematologic toxicity.

Results of the study showed that one patient had a complete response and 22 had partial response, for a combined overall response rate of 74.1%. Overall survival was 20.3 months and mean progression free survival was 8.1 months.

Safety analysis showed a total of 14 serious adverse events were recorded. The hematologic toxicities were in a majority of the cases self-limiting and manageable. Investigators concluded that "PHP Therapy with the Generation Two version of CHEMOSAT is an effective and safe treatment for patients with hepatic metastases from ocular melanoma."

The presentation at the European Conference, an Interventional Oncology updated data previously presented at the 2018 annual conference of the Cardiovascular and Interventional Radiological Society of Europe.

Market Access and Commercial Clinical Adoption

Europe

Delcath's European subsidiary, Delcath Systems, Ltd., is headquartered in Galway, Ireland. Our marketing strategy in the European Economic Area (the "EEA") includes establishing strategic alliances with partners that include license, supply, sales and marketing arrangements. In December 2018, Delcath entered into a definitive licensing agreement (the "medac License") for CHEMOSAT commercialization in Europe with medac Gesellschaft für klinische Spezialpräparate mbH ("medac"), a privately held, multi-national pharmaceutical company based in Wedel, Germany. Founded in 1970, medac specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases. medac has offices globally, worldwide partner agreements in over 90 countries, and approximately 1,200 employees.

Under the terms of the medac License, Delcath Systems, Ltd. exclusively licenses to medac the right to sell and market CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland, and the United Kingdom. The medac License provides for payment by medac to Delcath in a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

We believe that medac is a well-suited partner to help advance CHEMOSAT commercialization in the European Union and neighboring countries. medac has offices throughout Europe, a well-established network among oncology key opinion leaders, and organizational scale necessary to help establish CHEMOSAT in the European treatment landscape for cancers of the liver.

Since launching CHEMOSAT in Europe, over 700 commercial treatments have been performed at over 25 leading European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine. In 2017, we announced our first patient to receive eight CHEMOSAT treatments, and have seen the average number of repeat treatments performed on a per patient basis consistently increase.

During the quarter ended March 31, 2019 we continued to work closely with medac on advancement of the commercialization of CHEMOSAT in Europe. Medac has remained supportive during the first half of this year and is confident in the opportunities for CHEMOSAT in Europe.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups ("DRG") as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

Effective with the execution of our license agreement with medac, medac will provide support for reimbursement applications in the European markets covered by our agreement.

Germany

In October 2015, we announced that the Institut für das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a national Zusatzentgeld (ZE) reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group (DRG) code is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created and will replace the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually for reimbursement of their CHEMOSAT treatment. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany. Coverage levels under this process are negotiated between hospitals in Germany and regional sickness funds, with coverage levels renegotiated annually.

United Kingdom

In May 2014, the National Institute for Clinical Excellence ("NICE"), a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. Delcath expects to consult again with the Interventional Procedures Advisory Committee at NICE in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. medac will continue consultations begun by Delcath with the Interventional Procedures Advisory Committee at NICE in England, providing recent clinical evidence with a view to moving existing Interventional Procedural Guidance from a research recommendation to specialist recommendation. This would enable greater scope for commercialization access to the therapy because it would allow more use by National Health Service ("NHS") clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement within the NHS.

In the short term, public patients will continue to be treated in the UK through clinical trials. Private patients will continue to be treated through the established private treatment pathway such as private insurance coverage or self-pay.

Netherlands

In the Netherlands CHEMOSAT has been performed at the Netherlands Cancer Institute in 2013 and at Leiden University Medical Centre since 2014. In June 2017 the Medical Oncology National Treatment Guidelines for Uveal Melanoma were updated and now include recommendations to consider CHEMOSAT in the treatment of liver metastases. We are hopeful that inclusion in the national guidelines and the support of clinicians treating patients with CHEMOSAT will support an application for reimbursement in this market.

Regulatory Status

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated periodically, but at least annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor

may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the European Economic Area and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.

- Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

- Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor’s agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

Prior to initiating our currently ongoing Phase 3 clinical trial(s), we submitted a proposal for the design, execution and analysis under a SPA.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA’s goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny

approval of an NDA by issuing a Complete Response Letter (CRL) if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy (REMS) that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the FFDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

The FDA has granted Delcath six orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma, as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. In October 2013, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of HCC. In July 2015, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of cholangiocarcinoma, which includes ICC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all, or on a timely basis.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds rights in eight U.S. utility patents, one U.S. design patent, five pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validation of a European patent directed to our filter apparatus in eight European countries, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications. In July 2017, a patent directed to our chemotherapy filtration system was issued by the U.S. Patent and Trademark Office. In October 2018 and February 2019 patents directed to our chemotherapy filtration system and a method of using our filter and frame apparatus were issued by the United States Patent and Trademark Office. A Notice of

Allowance was obtained from the United States Patent and Trademark Office for the patent application entitled “Apparatus For Removing Chemotherapy Compounds from Blood” with allowed claims to a kit of parts capable of being assembled for delivering a small molecule chemotherapeutic agent to a subject. The allowed claims are directed to CHEMOSAT. A Hong Kong patent directed to our Filter and Frame Apparatus was issued in March of 2018. A European patent was granted for our chemotherapy filtration system in November 2018 and a European patent application directed to a method of using our filter and frame apparatus was granted in April 2019 by the European Patent Office.

When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT and Melphalan/HDS that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as beyond the treatment of cancers in the liver.

There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

In certain circumstances, United States patent law allows for the extension of a patent’s duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted Delcath five orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, the Company believes that it will provide us with added protection once commercialization of an orphan drug designated product begins.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against Delcath, the Company may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, Delcath plans to enforce its intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
7,022,097	Method For Treating Glandular Diseases and Malignancies	4/4/2006	Owned	6/24/2023
9,707,331	Apparatus For Removing Chemotherapy Compounds from Blood	7/18/2017	Owned	9/17/2034
10,098,997	Apparatus For Removing Chemotherapy Compounds from Blood	10/16/2018	Owned	11/7/2032
D708749	Dual Filter	7/8/2014	Owned	7/8/2028
9,314,561	Filter and Frame Apparatus and Method of Use	4/19/2016	Owned	2/7/2034
10,195,334	Filter and Frame Apparatus and Method of Use	2/5/2019	Owned	1/16/2033
9,541,544	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	1/10/2017	Owned	8/28/2033

Patent Applications in the United States

Application No.	Application Title	Filing Date	Owned or Licensed
16/127,008	Apparatus For Removing Chemotherapy Compounds from Blood	9/10/2018	Owned
16/231,486	Filter and Frame Apparatus and Method of Use	12/22/2018	Owned
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/8/2016	Owned

Foreign Patents

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
84.098	Dual Filter (Argentina)	6/29/2012	Owned	6/29/2027
343454	Dual Filter (Australia)	7/23/2012	Owned	6/25/2022
146201	Dual Filter (Canada)	5/15/2013	Owned	5/15/2023
ZL 201230277905.5	Dual Filter (China)	3/20/2013	Owned	6/22/2022
1333173	Dual Filter (Europe)	6/27/2012	Owned	6/25/2037
1456186	Dual Filter Cartridge for Fluid Filtration (Japan)	10/26/2012	Owned	10/26/2032
2797644	Filter and Frame Apparatus and Method of Use (Belgium)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (France)	4/12/2017	Owned	12/29/2032
602012031191.6	Filter and Frame Apparatus and Method of Use (Germany)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Great Britain)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Ireland)	4/12/2017	Owned	12/29/2032
502017000073120	Filter and Frame Apparatus and Method of Use (Italy)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Luxembourg)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Switzerland)	4/12/2017	Owned	12/29/2032
2776086	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/29/2018	Owned	11/7/2032
1203425	Filter and Frame Apparatus and Method of Use (Hong Kong)	3/23/2018	Owned	12/29/2032
3238762	Filter and Frame Apparatus and Method of Use (Europe)	4/17/2019	Owned	12/29/2032

Foreign Patent Applications

Application No.	Title	Filing Date	Owned or Licensed
17,176,952.400	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/7/2012	Owned
18164476.6	Filter and Frame Apparatus and Method of Use (Europe)	12/29/2012	Owned

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the

FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

European Regulatory Environment

In the EEA, the CHEMOSAT system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the CHEMOSAT system is governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments.

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a

conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable, it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

A manufacturer without a registered place of business in a Member State of the EU which places a medical device on the market under its own name must designate an Authorized Representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA. With the Delcath Systems Ltd. infrastructure now firmly in place, the Authorized Representative responsibilities have been formally transferred internally and there is no longer a need for a third-party representative.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the EU must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation

if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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 device in Europe to comply with the new medical device regulation ("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.

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.

Other International Regulations

We continue to evaluate commercial opportunities in select markets when resources are available and at an appropriate time.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of continued economic weakness, which is affecting healthcare budgets and reimbursement.

CHEMOSAT and Melphalan/HDS competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In the disease states we are targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of focal and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.

For ICC, gemcitabine plus cisplatin remains the standard of care for the treatment of ICC in patients who are not candidates for surgery.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar™, GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST™, GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease.

Many of these treatments are approved in Europe and other global markets.

Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials, regulatory, manufacturing and commercialization capabilities. Our competitors may develop alternative treatment methods, or achieve earlier product development, in which case the likelihood of us achieving meaningful revenues or profitability will be substantially reduced.

Manufacturing and Quality Assurance

We manufacture certain critical medical device components including our proprietary filter media and assemble and package the CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we conduct final manufacturing, processing and assembly. Delcath currently utilizes third-parties to manufacture some components of the CHEMOSAT and Melphalan/HDS. The CHEMOSAT and Melphalan/HDS and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process.

We are committed to providing high quality products to our customers. To honor this commitment, Delcath has implemented updated quality systems throughout our organization. Delcath’s quality system starts with the initial product specification and continues

through the design of the product, component specification process and the manufacturing, sale and servicing of the product. These systems are designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization (ISO) with respect to products sold in the EEA. The Company is required to maintain ISO 13485 certification for medical devices to be sold in the EEA, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. On February 17, 2011, we announced that we had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, we announced that we had achieved ISO 13485 certification for our Galway, Ireland facility. All Delcath manufacturing facilities are presently ISO 13485:2016 certified.

Recent Events

On July 11, 2019, the Company and certain accredited investors (each an "Investor" and, collectively, the "Investors") entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company expects to sell and issue to the Investors an aggregate of 20,000 shares of Series E Convertible Preferred Stock, par value $0.01 per share, at a price of $1,000 per share (the "Private Placement"). Pursuant to the Securities Purchase Agreement, the Company will issue to each Investor a warrant (a "Warrant") to purchase a number of shares of common stock of the Company, par value $0.01 per share ("Common Stock"), equal to the number of shares of Common Stock issuable upon conversion of the Series E Preferred Stock purchased by the Investor. Each Warrant will have an exercise price equal to $0.06, subject to adjustment in accordance with the terms of the Warrants (the "Exercise Price"), and be exercisable at any time beginning on the date that the Company effects a reverse stock split until 5:00 p.m. (NYC time) on the date that is five years following the date that the Company effects a reverse stock split. The Company expects to receive gross proceeds from the Private Placement of approximately $20.0 million, before deducting cash fees in the amount of $1.4 million payable to Roth Capital Partners, LLC ("Roth") for serving as placement agent for the Private Placement and cash fees in the amount of $552,000 payable to Roth for serving as placement agent for certain prior securities offerings by the Company, and other transaction costs, fees and expenses payable by the Company.

Results of Operations for the three months ended March 31, 2019; Comparisons of Results of Operations for three months ended March 31, 2018

Revenue

The Company recorded approximately $0.1 million in revenue related to product sales for the three months ended March 31, 2019 and $0.7 million in revenue related to product sales for the three months ended March 31, 2018. The decrease was slightly offset by $0.2 million in other revenue. Other revenue and the decrease in product revenue are both related to the Company entering into a licensing agreement with medac as discussed further in the Market Access and Commercial Clinical Adoption section above.

Cost of Goods Sold

For the three months ended March 31, 2019, the Company recorded cost of goods sold of approximately $0.1 million compared to $0.15 million for the three months ended March 31, 2018. The decrease of approximately $50,000 is related to an adjustment in the allocation of expenses into COGS during the three months ended March 31, 2019.

Selling, General and Administrative Expenses

For the three months ended March 31, 2019 and 2018, selling, general and administrative expenses were $2.5 million and $2.4 million, respectively. The increase for the three months ended March 31, 2019 is primarily related to non-cash personnel related accruals.

Research and Development Expenses

For the three month period ended March 31, 2019 and 2018, research and development expenses decreased to $3.3 million from $5.7 million. The decrease was primarily due a reduced rate of enrollment and related professional services related to the ongoing accrual of the Company's Phase 3 FOCUS trial which is discussed in further detail in the *Active Clinical Development Program* section above. The reduction is related to the cash constraints the Company experienced during the three months ended March 31, 2019.

Change in the fair value of the warrant liability

For the three months ended March 31, 2019 the change in the fair value of the warrant liability was approximately $7,000 as compared to $14.7 million for the three months ended March 31, 2018. The increase of $14.7 million is due to the reclassification of certain warrants from liability to equity in 2018 and the continued mark-to-market adjustments to the remaining Warrant liability as discussed in more detail in Note 10 to the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Other Income/Expense

Other expense and interest expense are primarily related to the amortization of debt discounts discussed in Note 8 of the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, as well as foreign currency exchange gains and losses.

Interest income is from a money market account and interest earned on operating accounts.

Net Loss

The Company recorded a net loss for the three months ended March 31, 2019 of $7.9 million, an increase of $15.1 million, or 209.8%, compared to net income of $7.2 million for the same period in 2018. This increase in net loss is primarily due to a $14.7 million change in the fair value of the warrant liability, a non-cash item, and a $2.2 million decrease in operating expenses.

Liquidity and Capital Resources

The Company's capital resources as of March 31, 2019 are not sufficient to fund planned operations during 2019. The Company will need to raise additional capital under structures available to it including debt and/or equity offerings this year. If these sources do not provide the capital necessary to fund the Company's operations, the Company will need to curtail certain aspects of its operations or consider other means of obtaining additional financing, although there is no guarantee that the Company could obtain the financing necessary to continue its operations.

The Company's future results are subject to substantial risks and uncertainties. As noted above, Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming years. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its clinical and operating activities. Delcath's 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.

At March 31, 2019, the Company had cash, cash equivalents and restricted cash totaling $1.3 million, as compared to cash, cash equivalents and restricted cash totaling $3.6 million at December 31, 2018 and $3.1 million at March 31, 2018. During the three months ended March 31, 2019 and 2018, the Company used $2.8 million and $6.4 million respectively, of cash in its operating activities.

Our condensed consolidated financial statements as of March 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to Ocular Melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of its business. Further, the Company's assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the timing, scope, focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements and public offerings of its securities in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016, 2018 and 2019, including registered direct offerings in 2007, 2009 and 2013, "at the market" equity offering programs in 2012 and 2013, and by the private placement of convertible notes in 2016 and 2018, and, most recently, on July 15, 2019, the Company raised $20.0 million in the closing of a private placement of convertible preferred stock and warrants to purchase common stock. For a detailed discussion of the Company's various sales of debt and equity securities see Notes 8, 9, and 14 to the Company's financial statements contained in this Quarterly Report on Form 10-Q as well as Notes 10 and 11 to the Company's audited consolidated financial statements contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

In October 2018, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allowed the Company to offer and sell, from time to time in one or more offerings, up to $100.0 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company has lost its Form S-3 eligibility due to the late filing of its Form 10-K for the year ended December 31, 2018.

The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, funding of clinical trials, obtaining regulatory approvals, commercialization of its products, capital expenditures and working capital.

Application of Critical Accounting Policies

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found 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, 2018.

Item 3.Quantitative and Qualitative Disclosures about Market Risk

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

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

In February 2018, the Company completed the sale of 424,000 shares of its common stock and the issuance of warrants to purchase 1.0 million common shares (the "February 2018 Warrants") pursuant to a placement agent agreement. The Company received net proceeds of $4.6 million, with cash proceeds after related expenses from this transaction of $4.3 million. The Company allocated an estimated fair value of $18.3 million to the February 2018 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At March 31, 2019, the February 2018 Warrants had an exercise price of $10.00 per share with 189,000 warrants outstanding. The February 2018 Warrants have a six-year term and are not exercisable until the first anniversary of issuance.

The proceeds allocated to the February 2018 Warrants were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As discussed in Part II – Item 1 "Legal Proceedings" and in Note 12 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, the February 2018 Warrants will be surrendered pursuant to a settlement agreement entered into between the Company and the holders of the February 2018 Warrants on April 18, 2019. The fair value of the Warrants at March 31, 2019 was determined by using option pricing models assuming the following:

	March 31, 2019	December 31, 2018
Expected life (in years)	4.75	1.13 - 5.11
Expected volatility	146.4%	145.7% - 265.3%
Risk-free interest rates	2.2%	2.5% - 2.6%

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its Chief Executive Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act). Based on that evaluation, the Company's Chief Executive Officer concluded that Delcath's disclosure controls and procedures as of March 31, 2019 (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 by us in the Company's 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 the Company's Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2019 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

As previously reported, on March 26, 2019, the Company commenced an action (the "Action") in the Commercial Division of the Supreme Court for the State of New York, County of New York, styled as Delcath Systems, Inc., v. Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd., L1 Capital Global Opportunities Master Fund and First Fire Global Opportunities Fund LLC (Index No. 651749/2019). The Action seeks expedited equitable relief in the form of reformation and a declaratory judgement to remedy a scrivener's error in the Series D Warrants issued in the Company's February 2018 public offering such that those warrant do not contain a price and quantity ratchet upon a sale of Company securities at a price lower than the offering price in the February 2018 offering. The defendant, L1 Capital Global Opportunities Master Fund, settled with the Company by exchanging its Series D Warrants for Company common stock on a one-for-one basis, which is the same ratio for which other investors in the February 2018 round exchanged their Series D Warrants in December 2018. The Company and the remaining defendants in the Action, Iroquois Capital Investment Group LLC, Iroquois Master Fund Ltd. and First Fire Global Opportunities Fund LLC, entered into a settlement agreement on April 18, 2019, pursuant to which such defendants surrendered the Series D Warrants and waived all rights granted to them by or in connection with the Series D Warrants and all rights afforded to them to participate in the Company's future common stock offerings. In consideration therefor, pursuant to the settlement agreement, (i) the Company paid one-fifth of the reasonable fees and expenses of defendants' counsel incurred in connection with the Action and negotiation of the settlement agreement, the total of which shall not exceed $50,000 (the "Settlement Fees") and (ii) subject to the Company securing and closing certain contemplated financing, the Company agreed to pay to the defendants $400,000 and the remaining Settlement Fees. On July 17, 2019, the Company paid the amount of $440,000 to the defendants pursuant to the settlement agreement from the net proceeds received by the Company in a closing of a private placement transaction discussed in Note 14 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

On May 9, 2018, the Company received a Demand Letter from a vendor for an outstanding balance owed at that time of $2.1 million. The Company has worked with the vendor since that time to establish a payment plan for the balance owed.

Item 1A.Risk Factors

Delcath's 2018 Annual Report on Form 10-K, in Part 1 – Item 1A. "Risk Factors," contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition.

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

None.

Item 3.Defaults upon Senior Securities

On April 15, 2019, the Company received a notice of default from Discover Fund with respect to various unspecified defaults under its promissory notes issued to Discover on June 4, 2018, July 20, 2018, August 31, 2018 and March 28, 2019 (the "Notes"). The notice states that Discover has opted to accelerate the Notes at the Default Amount (as defined in the Notes). The outstanding principal prior to the notice of default was $5.6 million. The Notes were subsequently assigned to Rosalind Master Fund LP by Discover Growth Fund and Discover Growth Fund, LLC. Thereafter, on July 16, 2019, pursuant to an exchange agreement among the Company and Rosalind Master Fund LP and Rosalind Opportunities Fund I LP, the Notes were exchanged for Series E Convertible Preferred Stock and new warrants to purchase Common Stock subsequent to the closing of the private placement transaction discussed in Note 14 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

On April 24, 2019, the Company received a notice of default with regard to the 8% Senior Secured Convertible Notes due March 21, 2019 (the "2019 Notes") and the 8% Senior Secured Notes due March 21, 2020 (the "2020 Notes") held by District 2 Capital Fund LP ("District Capital") and Bigger Capital Fund, LP ("Bigger Capital") with respect to specified defaults. The notice stated that District Capital and Bigger Capital have opted to accelerate those Notes at the Default Amount as defined in those notes. The outstanding principal prior to the notice of default was $0.5 million. Thereafter, on July 15, 2019, pursuant to an exchange agreement among the Company and District Capital and Bigger Capital, the 2019 Notes and the 2020 Notes held by District Capital and Bigger Capital were exchanged for Series E Convertible Preferred Stock and new warrants to purchase Common Stock in the closing of the private placement transaction discussed in Note 14 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Item 4.Mine Safety Disclosures

Not Applicable.

Item 5.Other Information

Not Applicable.

Item 6.Exhibits

Exhibit No.		Description
31.1	**	Certification by Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	**	Certification by Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	***	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	***	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		XBRL Taxonomy Extension Label Linkbase Document
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document

** Filed herewith.

*** Furnished herewith.

DELCATH SYSTEMS, INC.

SIGNATURES

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

July 17, 2019

DELCATH SYSTEMS, INC.
(Registrant)

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

Exhibit 31.1

DELCATH SYSTEMS, INC.

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jennifer K. Simpson, Chief Executive Officer, certify that:

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

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

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

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

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

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

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

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

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

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

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

July 17, 2019

/s/ Jennifer K. Simpson

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

Exhibit 31.2

DELCATH SYSTEMS, INC.

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Barbra C. Keck, Principal Financial Officer, certify that:

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

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

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

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

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

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

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

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

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

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

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

July 17, 2019

/s/ Barbra C. Keck

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

Exhibit 32.1

DELCATH SYSTEMS, INC.

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jennifer K. Simpson, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

July 17, 2019

/s/ Jennifer K. Simpson

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

Exhibit 32.2

DELCATH SYSTEMS, INC.

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barbra C. Keck, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

July 17, 2019

/s/ Barbra C. Keck

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