DELCATH SYSTEMS, INC.
Form 10-Q
November 13, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

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)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Securities Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 8, 2018, 9,007,952 shares of the Company’s common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Table of Contents

		Page
PART I—FINANCIAL INFORMATION		
Item 1.	Financial Statements (Unaudited)	
	Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017	4
	Condensed Consolidated Statement of Stockholders' Deficit for the nine months ended September 30, 2018	5
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	39
Item 4.	Controls and Procedure	39
PART II—OTHER INFORMATION		
Item 1.	Legal Proceedings	40
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	40
Item 3.	Defaults upon Senior Securities	40
Item 4.	Mine Safety Disclosure	40
Item 5.	Other Information	40
Item 6.	Exhibits	41
SIGNATURES		42

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 8,913	$ 3,999
Restricted cash	1,062	1,325
Accounts receivables, net	364	317
Inventories	954	1,248
Prepaid expenses and other current assets	527	700
Total current assets	11,820	7,589
Property, plant and equipment, net	1,012	1,298
Total assets	$ 12,832	$ 8,887
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 6,783	$ 3,846
Accrued expenses	6,125	3,408
Current portion of convertible notes payable, net of debt discount	2,664	—
Warrant liability	1,475	560
Total current liabilities	17,047	7,814
Convertible notes payable, net of current portion and debt discount	116	—
Other non-current liabilities	534	395
Total liabilities	17,697	8,209
Commitments and Contingencies	—	—
Stockholders' (deficit) equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 5,694,437 and 263,275 shares issued and 5,694,436 and 263,274 shares outstanding at September 30, 2018 and December 31, 2017, respectively*	57	3
Additional paid-in capital	328,209	325,516
Accumulated deficit	(333,185)	(324,832)
Treasury stock, at cost; 1 share at September 30, 2018 and December 31, 2017, respectively*	(51)	(51)

Accumulated other comprehensive income	105	42
Total stockholders' (deficit) equity	(4,865)	678
Total liabilities and stockholders' equity	$ 12,832	$ 8,887

*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and 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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Revenue	$824	$684	$2,384	$2,011
Cost of goods sold	233	172	600	527
Gross profit	591	512	1,784	1,484
Operating expenses:				
Selling, general and administrative	2,279	2,860	7,286	7,807
Research and development	4,106	2,279	13,886	7,119
Total operating expenses	6,385	5,139	21,172	14,926
Operating loss	(5,794)	(4,627)	(19,388)	(13,442)
Change in fair value of the warrant liability, net	1,198	27	18,407	1,227
Gain on warrant extinguishment	—	—	—	9,613
Loss on debt extinguishment	(1,123)	(2,952)	(1,123)	(2,952)
Loss on issuance of financial instrument	—	—	(2,826)	—
Interest expense	(3,151)	(5,042)	(3,402)	(20,324)
Other (expense) income	(10)	(2)	(21)	5
Net loss	$(8,880)	$(12,596)	$(8,353)	$(25,873)
Other comprehensive loss:				
Foreign currency translation adjustments	105	(15)	63	7
Comprehensive loss	$(8,775)	$(12,611)	$(8,290)	$(25,866)
Common share data:				
Basic loss per common share*	$(0.25)	$(4,565)	$(0.60)	$(17,313)
Diluted loss per common share*	$(0.25)	$(4,565)	$(0.64)	$(17,313)
Weighted average number of basic shares outstanding*	35,859,866	2,763	13,888,577	1,494
Weighted average number of diluted shares outstanding*	35,859,866	2,763	13,888,587	1,494

*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

See accompanying Notes to Condensed Consolidated Financial Statements.

4

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Stockholders' Deficit

(Unaudited)

(in thousands, except share data)

	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	263,275	$ 3	(1)	$ (51)	$ 325,516	$ (324,832)	$ 42	$ 678
Compensation income for issuance of stock options	—	—	—	—	(40)	—	—	(40)
Compensation expense for issuance of restricted stock	60,000	1	—	—	34	—	—	35
Sale of common stock, net of expenses	5,336,665	53	—	—	11,224	—	—	11,277
Cashless exercise of warrants	34,497	—	—	—	—	—	—	-
Issuance of pre-funded warrants	—	—	—	—	520	—	—	520
Fair value of warrants issued in Feb 2018 public offering	—	—	—	—	(18,306)	—	—	(18,306)
Fair value of warrants issued with Convertible Notes	—	—	—	—	5,007	—	—	5,007
Fair value of warrants reclassified from liability to equity	—	—	—	—	4,210	—	—	4,210
Beneficial conversion feature of convertible note	—	—	—	—	44	—	—	44
Net loss	—	—	—	—	—	(8,353)	—	(8,353)
Total comprehensive loss	—	—	—	—	—	—	63	63
Balance at September 30, 2018	5,694,437	$ 57	(1)	$ (51)	$ 328,209	$ (333,185)	$ 105	$ (4,865)

See accompanying Notes to Condensed Consolidated Financial Statements.

5

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine months ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(8,353)	$(25,873)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation (income) expense	(40)	48
Restricted stock compensation expense	35	84
Depreciation expense	342	198
Loss on disposal of equipment	—	20
Warrant liability fair value adjustment	(18,407)	(1,227)
Gain on warrant extinguishment	—	(9,613)
Non-cash interest income	(2)	16
Deferred revenue	—	(30)
Debt discount amortization	3,381	20,315
Loss on issuance of financial instrument	2,826	—
Loss on debt extinguishment	1,123	2,952
Changes in assets and liabilities:		
Prepaid expenses and other assets	171	276
Accounts receivable	(60)	(94)
Inventories	289	(338)
Accounts payable and accrued expenses	5,662	1,767
Other non-current liabilities	139	(160)
Net cash used in operating activities	(12,894)	(11,659)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(59)	(372)
Net cash used in investing activities	(59)	(372)
Cash flows from financing activities:		
Expenses from the release of restricted cash	—	(788)
Cash paid to extinguish of Series C Warrants	—	(7,876)
Net proceeds from sale of Series B and Series C preferred shares	—	2,278
Redemption of Series A and Series B preferred shares	—	(2,360)
Net proceeds from convertible note debt financing	5,727	—
Net proceeds from sale of common stock and pre-funded warrants	11,797	15
Net cash provided by financing activities	17,524	(8,731)
Foreign currency effects on cash, cash equivalents and restricted cash	80	(77)
Net decrease in cash, cash equivalents and restricted cash	4,651	(20,839)

Cash, cash equivalents and restricted cash:		
Beginning of period	5,324	31,696
End of period	$9,975	$10,857
Supplemental non-cash financing activities:		
Conversion of convertible notes to common stock	$—	$26,199
Fair value of warrants issued	$28,539	$—
Fair value of warrants exercised	$—	$19

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

(1) General

The unaudited interim condensed consolidated financial statements of Delcath Systems, Inc. ("Delcath" or the "Company") as of and for the three and nine months ended September 30, 2018 and 2017 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, 2017 ("Annual Report"), which has been filed with the Securities Exchange Commission ("SEC") on March 16, 2018 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 CHEMOSAT and Melphalan/HDS is comprised of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial), a Global Phase 3 clinical trial that is investigating objective response rate in mOM, and The ALIGN Trial, a registration trial for intrahepatic cholangiocarcinoma (ICC). Our CDP also includes a commercial registry for CHEMOSAT non-clinical 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 for a reasonable period of time.

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 September 30, 2018 and 2017; 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.

Reverse Stock Split

On May 2, 2018, the Company effected a reverse stock split at which time Delcath's common stock began trading on the OTCQB on a one-for-five hundred (1:500) split-adjusted basis. All owners of record as of the open of the OTCQB market on May 2, 2018 received one issued and outstanding share of Delcath common stock in exchange for five hundred outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-five hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company's consolidated financial statements contained in this Annual Report on Form 10-K and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

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, 2017.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers ("ASU 2014-09") that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

On January 1, 2018, the Company adopted ASU 2014-09 using the modified retrospective method and the impact was determined to be immaterial on its consolidated financial statements. The new revenue standard was applied prospectively in Delcath's condensed consolidated financial statements from January 1, 2018 forward and reported financial information for historical comparable periods will not be revised and will continue to be reported under the accounting standards in effect during those historical periods.

Delcath generates revenue from the sales of its product in Europe, where its system is commercially available under the trade name Delcath Hepatic CHEMOSAT Delivery System for Melphalan ("CHEMOSAT®"). Revenue from product sales is generally recognized at the time of shipment to a treating center or distributor, when control of the promised goods has been transferred to our customers. When obligations or contingencies remain after the products are shipped, such as training and certifying new treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Delcath has one distribution contract with a Turkish distributor. The contract has standard provisions for termination, renewal, limited warranty and right of return. CHEMOSAT kits are delivered to the Turkish distributor as orders are received and revenue is recognized at the time of shipment to the distributor. Delcath sells directly to centers in Europe with the exception of those centers located in Turkey. Sales are processed when purchase orders are received from the hospitals and revenue is recognized at the time of shipment to the treating center.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be

required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company adopted this standard on January 1, 2018.

In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including interim periods within those fiscal years. An entity that elects early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The adoption of this standard did not have a material impact on the Company’s financial statements.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases, which requires entities to report a right-to-use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve months or less. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is currently evaluating the impact it may have on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815). The new guidance intends to reduce the complexity associated with the issuer’s accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the Board determined that a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. In addition, the Board re-characterized the indefinite deferral of certain provisions of Topic 480 to a scope exception. The re-characterization has no accounting effect. ASU 2017-11 is effective for public entities for fiscal years beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company’s consolidated financial statements.

SEC Disclosure Update and Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.

(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.

Restricted cash balances were as follows:

	September 30,	December 31,

(in thousands)	2018	2017
Cash and cash equivalents	$ 8,913	$ 3,999
Convertible Notes	—	238
Letters of credit	1,012	1,012
Security for credit cards	50	75
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 9,975	$ 5,324

(3) Inventories

Inventories consist of the following:

(in thousands)	September 30, 2018	December 31, 2017
Raw materials	$ 389	$ 298
Work-in-process	454	721
Finished goods	111	229
Total inventories	$ 954	$ 1,248

(4) Prepaid Expenses and Other Current Assets
Prepaid expenses and other current assets consist of the following:

(in thousands)	September 30, 2018	December 31, 2017
Outside consultants	$ 249	$ —
Taxes receivable	145	29
Insurance premiums	52	421
Security deposit	51	50
Software	19	15
Financing costs	—	70
Other[1]	11	115
Total prepaid expenses and other current assets	$ 527	$ 700

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at September 30, 2018 and December 31, 2017.

(5) Property, Plant, and Equipment
Property, plant, and equipment consist of the following:

(in thousands)	September 30, 2018	December 31, 2017
Buildings and land	$ 589	$ 579
Enterprise hardware and software	1,742	1,744
Leaseholds	1,704	1,705
Equipment	985	971
Furniture	199	175
Property, plant and equipment, gross	5,219	5,174
Accumulated depreciation	(4,207)	(3,876)
Property, plant and equipment, net	$ 1,012	$ 1,298

Depreciation expense for the three and nine months ended September 30, 2018 was approximately $0.1 million and $0.3 million, respectively, as compared to approximately $0.1 million and, $0.2 million respectively, for the same period in 2017.

(6) Accrued Expenses
Accrued expenses consist of the following:

(in thousands)	September 30, 2018	December 31, 2017
Compensation, excluding taxes	$ 2,362	$ 869
Clinical trial expenses	2,793	1,124
Professional fees	521	221
Short-term portion of lease restructuring	189	209
Other[1]	260	985
Total accrued expenses	$ 6,125	$ 3,408

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at September 30, 2018 and December 31, 2017.

(7) Restructuring Expenses
In order to help reduce operating costs and more appropriately align its office space with the size of its workforce, the Company entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement (“Sub-lease #1”) for approximately one-half of the office space at this location (“Suite 3500”), resulting in

a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement ("Sub-lease #2") for the remaining one-half of office space at its 810 Seventh Avenue office ("Suite 3505"), resulting in a lease restructuring reserve of approximately $0.7 million.

The following table provides the year-to-date activity of the Company's restructuring reserves as of September 30, 2018:

(in thousands)	Lease Liability
Reserve balance at December 31, 2017	$ 604
Charges	—
Payments/Utilizations	(159)
Reserve balance at September 30, 2018	$ 445

(8) Secured Convertible Notes and related Common Stock Purchase Warrants
Convertible Notes, Net consisted of the following at September 30, 2018:

(in millions)	Interest rate	Conversion price	Principal	Unamortized Discount	Net Amount	Accrued Interest
June 2018 Convertible Note, as amended[1]	8.0%	$ 1.75	$ 3.4	$ (1.5)	$ 1.9	$ 0.1
July 2018 Convertible Note, as amended[2]	8.0%	1.75	2.2	(1.7)	0.5	0.01
August 2018 Convertible Note[3]	8.0%	1.75	3.3	(2.9)	0.4	0.01
September 2018 Convertible Note[4]	8.0%	1.75	0.5	(0.5)	—	—
Total Convertible Notes Payable, Net			$ 9.4	$ (6.6)	$ 2.8	$ 0.1

[1] The June 2018 Convertible Note matures as follows: 75% on December 4, 2018; 25% on December 4, 2019

[2] The July 2018 Convertible Note matures as follows: 75% on January 20, 2019; 25% on January 20, 2020

[3] The August 2018 Convertible Note matures as follows: 75% on March 1, 2019; 25% on March 1, 2020

[4] The September 2018 Convertible Note matures as follows: 75% on March 21, 2019; 25% on March 21, 2020

June 2018 Convertible Note

In June 2018, the Company entered into a Securities Purchase Agreement (the "June 2018 SPA") with an institutional investor pursuant to which the Company issued $3.3 million in principal face amount of senior secured convertible notes of the Company (the "June 2018 Notes") and related June 2018 Series D Warrant and June 2018 Pre-Funded Series D Warrants (the "June 2018 Series D Warrants") to purchase additional shares of the Company's common stock. June 2018 Notes in the amount of $3.3 million and June 2018 Pre-Funded Warrants in the amount of $0.2 million

were issued for cash proceeds of $2.4 million with an original issue discount in the amount of $1.1 million. The June 2018 Notes bear 8% interest payable upon maturity. Of the $3.3 million in issued June 2018 Notes, $2.5 million matures in six months; the balance of $0.8 million is payable in twelve installments beginning seven months after the original issuance date. Each payment shall be paid in cash or, provided that the Market Price (as defined in the June 2018 SPA) is at least the conversion price of $3.00, at the option of the Company, upon ten Trading Days' written notice to the Holder, in free trading common stock at the conversion price.

In connection with the issuance of the June 2018 Notes, the Company also issued June 2018 Series D Warrants. At issuance, the June 2018 Series D Warrant was exercisable to acquire 1.1 million shares of Common Stock at an initial exercise price of $4.00 and the June 2018 Pre-Funded Series D Warrants were exercisable to acquire 13.0 million shares of Common Stock at a pre-funded exercise price of $0.01. The Company was initially able to buy back each June 2018 Pre-Funded Series D Warrant on its date of initial exercisability so long as the Company was not in default and the applicable installment payment for each month had been paid when due. In the event that Delcath's Market Price (as defined in the Note Agreement) was less than $3.00, the Company could only purchase back these warrants if the June 2018 Notes payable were settled for cash. The provisions in the June 2018 Series D Warrants required the Company to initially account for the warrants as derivative liabilities. The Company valued the June 2018 Series D Warrants using the following inputs:

	June 2018 Series D Warrant	June 2018 Pre-Funded Series D Warrants
Expected life (in years)	5.0	5.5 - 6.5
Expected volatility	194.10%	215.0% - 389.0%
Risk-free interest rates	2.78%	2.13% - 2.30%

The Company recognized a discount to debt of $2.3 million and additional expense of $2.8 million was recognized as a Loss on issuance of a financial instrument related to the initial fair value of the June 2018 Series D Warrants. The June 2018 Series D Warrant has a five-year term; the June 2018 Pre-Funded Series D Warrants have a five-year term from initial exercisability which was to begin on the fifth day of each month commencing December 5, 2018, through December 5, 2019, for each of Warrant D-1-201 through 213 respectively.

July 2018 Convertible Note

In July 2018, the Company entered into a second Securities Purchase Agreement (the “July 2018 SPA”) with another institutional investor for the remaining Notes and Warrants in proportionate amounts to those issued in the June 2018 transaction. July 2018 Notes in the amount of $2.2 million and July 2018 Pre-Funded Series D Warrants in the amount of $0.1 million were issued for cash proceeds of $1.6 million with an original issue discount in the amount of $0.7 million. Of the $2.2 million in issued July 2018 Notes, $1.6 million matures in six months; the balance of $0.6 million is payable in twelve installments beginning seven months after the original issuance date.

In connection with the issuance of the July 2018 Notes, the Company also issued July 2018 Series D Warrants. At issuance, the July 2018 Series D Warrant was exercisable to acquire 0.8 million shares of Common Stock at an initial exercise price of $4.00 and the July 2018 Pre-Funded Series D Warrants were exercisable to acquire 9.2 million shares of common stock at a pre-funded exercise price of $0.01. The Company recognized discounts to debt of $1.4 million related to the initial fair value of the July 2018 Series D Warrants and $0.2 million related to debt financing costs.

First Amendment to June 2018 Series D Warrants

In July 2018, the Company and the investor from the June 2018 transaction amended the June 2018 Pre-Funded Series D Warrants so that they are exercisable as of July 20, 2018 and the Company may redeem them at any time the Notes are no longer outstanding and the Company is not in default. The Company and the investor from the June 2018 transaction also amended the definition of a Fundamental Transaction in the June 2018 Series D Warrants. This amendment resulted in $4.2 million related to the fair value of the June 2018 Series D Warrants being reclassified from a liability to equity.

August 2018 Convertible Note

In August 2018, the Company entered into an agreement to sell up to $6.0 million purchase price of its 8% Senior Secured Convertible Notes and Series D Warrants and Series D Pre-Funded Warrants pursuant to a Securities Purchase Agreement with one or more institutional investors. The Agreement has substantially the same terms as the June 2018 SPA and July 2018 SPA, except that the conversion price under the Notes and exercise price of the Warrants is $1.75, and interest on the Notes shall accrue and be payable at maturity.

In August 2018, Notes in the amount of $3.3 million (the “August 2018 Notes”) and August 2018 Pre-Funded Series D Warrants in the amount of $0.2 million were issued for cash proceeds of $2.5 million with an original issue discount in the amount of $1.1 million. Of the $3.3 million in issued August 2018 Notes, $2.5 million matures in six months; the balance of $0.8 million is payable in twelve installments beginning seven months after the original issuance date.

In connection with the issuance of the August 2018 Notes, the Company also issued August 2018 Series D Warrants. At issuance, the August 2018 Series D Warrant was exercisable to acquire 2.0 million shares of common stock at an initial exercise price of $1.75 and the August 2018 Pre-Funded Series D Warrants were exercisable to acquire 23.8 million shares of common stock at a pre-funded exercise price of $0.01. The Company recognized discounts to debt of $2.1 million related to the initial fair value of the August 2018 Series D Warrants and $0.1 million related to debt financing costs.

Amendment to June 2018 and July 2018 Notes and Pre-Funded Warrants

In August 2018, the Company amended its June 2018 Notes and July 2018 Notes such that the conversion price was reduced to $1.75, interest shall accrue until maturity, and the first $2.5 million and 50% of any subsequent financings shall be used to satisfy the Company’s obligations under the Notes. Effective the same date, the Company also amended its Pre-Funded Warrants such that the total number of June 2018 Pre-Funded Warrants was increased from 13.0 million to 22.2 million and the total number of July 2018 Pre-Funded Warrants was increased from 9.2 million to 15.8 million. This amendment was accounted for as an extinguishment of debt as the change in cash flows exceeded 10%. The original June 2018 and July 2018 notes were written off and the amended June 2018 and July 2018 Notes were recorded at fair value as of the date of this amendment. The Company recorded $1.1 million loss on debt extinguishment related to this amendment.

September 2018 Convertible Note

In September 2018, the Company entered into a SPA with another institutional investor for a remaining portion of the August 2018 Notes and Warrants. September 2018 Notes in the amount of $0.5 million and September 2018 Pre-Funded Warrants in the amount of $0.03 million were issued for cash proceeds of $0.4 million with an original issue discount in the amount of $0.2 million. Of the $0.5 million in issued September 2018 Notes, $0.4 million matures in six months; the balance of $0.1 million is payable in twelve installments beginning seven months after the original issuance date.

In connection with the issuance of the September 2018 Notes, the Company also issued September 2018 Series D Warrants. At issuance, the September 2018 Series D Warrant was exercisable to acquire 0.3 million shares of common stock at an initial exercise price of $1.75 and the September 2018 Pre-Funded Warrants were exercisable to acquire 3.1 million shares of common stock at a pre-funded exercise price of $0.01. The Company recognized a discount to debt of $0.4 million related to the initial fair value of the September 2018 Series D Warrants.

All of the Notes between June 2018 and September 2018 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.

Pursuant to the Amendment to the June 2018 and July 2018 Notes discussed above, the Company repaid $4.9 million of outstanding Notes during the first week of October 2018.

(9) Stockholders’ Equity
Stock Issuances

Reverse Stock Split

On May 2, 2018, the Company effected a reverse stock split at which time Delcath’s common stock began trading on the OTCQB on a one-for-five hundred (1:500) split-adjusted basis. All owners of record as of the open of the OTCQB market on May 2, 2018 received one issued and outstanding share of Delcath common stock in exchange for five hundred outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-five hundred exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company’s consolidated financial statements contained in this Quarterly Report on Form 10-Q and the accompanying Notes have been restated to give retrospective presentation for the reverse stock split.

February 2018 Financing

In February 2018, the Company completed the sale of 424,000 shares of its common stock, 76,000 pre-funded warrants and the issuance of warrants to purchase 1.0 million common shares (the “February 2018 Warrants”) pursuant to a placement agent agreement, with net proceeds after expenses of $4.3 million. The February 2018 Warrants are exercisable one year after the anniversary date of their issuance. At September 30, 2018, the February 2018 Warrants were exercisable at $10.00 per share with 1.0 million warrants outstanding. The Company allocated an estimated fair value of $18.3 million to the February 2018 Warrants. The Company valued the February 2018 Warrants using the following inputs: exercise price of $10.00; contractual term of six years; volatility of 122.68% and risk-free rate of

approximately one percent. Due to certain price protection features in the agreement, the February 2018 Warrants were accounted for as a derivative liability at issuance and will be subsequently marked to market through the statement of operations.

September 2018 Rights Offering

In September 2018, the Company completed the sale of 4,667,811 shares of its common stock, with net proceeds after expenses of approximately $7.0 million.

Stock Incentive Plans

As a result of the May 2, 2018 reverse stock split, the Company's Stock Incentive Plans has no active grants and no further shares available to be granted.

For the three and nine months ended September 30, 2018, the Company recognized compensation income of $0 and $40,000 relating to stock options granted to employees. For the same period in 2017, the Company recognized compensation expense of approximately $3,000 and $48,000 respectively.

For the three and nine months ended September 30, 2018, the Company recognized compensation expense of approximately $1.0 million and $35,000 relating to restricted stock granted to employees and consultants. For the same period in 2017, the Company recognized compensation expense of approximately $20,000 and $0.1 million, respectively.

Warrants

The following is a summary of warrant activity for the nine months ended September 30, 2018:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2017	14,049	$1,225 - $19,712,000	$ 13,942.79	4.88
Warrants issued in Feb 2018 registered direct offering	1,076,002		9.33	
Warrants issued with convertible notes	69,169,756		0.18	
Exercised	(74,010)		0.50	
Expired	—		—	
Outstanding at September 30, 2018	70,185,797	$0.01 - $19,712,000	$ 2.85	6.00

(10) Fair Value Measurements

The table below presents the activity within Level 3 of the fair value hierarchy for the nine months ended September 30, 2018:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2017	$560
Fair value of warrants issued	18,306
Total change in the liability included in earnings	(14,697)
Balance at March 31, 2018	4,169
Fair value of warrants issued	5,226

Total change in the liability included in earnings	(2,512)
Balance at June 30, 2018	6,883
Reclass from liability to equity	(4,210)
Total change in the liability included in earnings	(1,198)
Balance at September 30, 2018	$1,475

Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at September 30, 2018 and December 31, 2017 was determined by using option pricing models with the following assumptions:

	September 30, 2018	December 31, 2017
Expected life (in years)	0.08 - 5.36	0.82 - 4.88
Expected volatility	139.47% - 258.34%	130.88% - 266.92%
Risk-free interest rates	2.12% - 2.97%	1.68% - 2.06%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2018, 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	
	September 30, 2018	December 31, 2017	September 30, 2018	December 31, 2017	September 30, 2018	December 31, 2017	September 30, 2018	December 31, 2017
Liabilities								
Derivative instrument liabilities	$—	$ —	$ —	$ —	$1,475	$ 560	$1,475	$ 560

For the periods ended September 30, 2018 and 2017, 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.

	September 30,	
(in thousands, except share data)	2018	2017
Net loss - basic	(8,353)	(25,873)
Adjustment for gain on warrant income	(534)	—
Net loss - diluted	$(8,887)	$(25,873)
Weighted average shares outstanding - basic	13,888,577	1,494
Weighted average shares outstanding - diluted	13,888,587	1,494
Net loss per share - basic	$(0.60)	$(17,313)
Net loss per share - diluted	$(0.64)	$(17,313)

The following potentially dilutive securities were excluded from the computation of earnings per share as of September 30, 2018 and 2017 because their effects would be anti-dilutive:

	September 30, 2018	2017
Common stock warrants - equity	4,202,909	—
Common stock warrants - liability	1,000,011	38
Assumed conversion of convertible notes	5,639,318	—
Total	10,842,238	38

(12) Taxes

As discussed in Note 13 Income Taxes of the Company's Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company's federal income tax return for the year ended December 31, 2013. The examination was completed in the third quarter of 2017 and no changes were made to the

reported amounts. Accordingly, there was no effect on the financial statements as a result of the examination. 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 13 Income Taxes of the Company's Annual Report.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the Tax Act) was enacted into law and the new legislation contains several key tax provisions that affected us, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. We were required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring our U.S. deferred tax assets and liabilities as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting of deferred tax re-measurements and the transition tax to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions. As of September 30, 2018, the Company completed its assessment of the tax effects of the Tax Act. The Company determined a SAB 118 measurement period adjustment was not necessary.

In October 2016, the Financial Accounting Standards Board ("FASB") issued accounting standards update 2016-16 which simplifies the income tax consequences of intra-entity transfers other than inventory. Prior to ASU 2016-16, GAAP prohibited the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. ASU 2016-16 eliminates this prohibition for intra-entity transfers of assets other than inventory but retain the prohibition for intra-entity transfers of inventory. This standard is effective for public entities for fiscal years beginning after December 15, 2017. The Company adopted ASU 2016-16, effective on January 1, 2018. As a result of adoption, the Company recognized a $834 decrease to its net operating loss deferred tax assets, offset by a $834 decrease to the corresponding valuation allowance.

(13) Commitment and Contingencies

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the "Suit"). The Suit alleges breaches by the Company of Hudson Bay's rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. The Company denies any liability with respect to the claims set forth in the Suit.

(14) Subsequent Events

Cash outflow financing activities

Pursuant to the Amendment to the June 2018 and July 2018 Notes discussed above, the Company repaid $4.9 million of outstanding Notes during the first week of October 2018.

Series D Preferred Stock

On November 5, 2018, our 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 (the "Series D Certificate of Designations") which was filed with the State of Delaware on November 5, 2018 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the "Series D Preferred Stock").

On November 6, 2018, the Company entered into a stock purchase agreement (the "SPA") with an institutional investor who purchased 85 shares of Series D Preferred Stock (the "Series D Preferred Stock") at a purchase price of $10,000 per share. The purchase of the Series D Preferred Stock is being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended. The Series D Preferred Stock convert into shares of our common stock at a per common share conversion price of $0.61. The Series D Preferred Stock has no dividend, liquidation or other preferential rights to Delcath's common stock.

Warrant exercises

Subsequent to September 30, 2018 through November 8, 2018, 3.3 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 Company's financial condition and results of operations 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 financial statements and notes thereto as of and for the year ended December 31, 2017 included in the Company's 2017 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 June 30, 2018 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," 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 June 30, 2018 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 September 30, 2018 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, 2017 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/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/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 2017 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 intrahepatic cholangiocarcinoma (ICC). 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/Melphalan/HDS is informed by; prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on patients in Europe, and prior regulatory experience 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, HCC 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 8.2 million deaths and 14.1 million new cases in 2012 according to GLOBOCAN. 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 U.S. in 2014 was $87.8 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 intrahepatic bile duct cancers or 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 we commissioned in 2016, 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 (SOC) for patients with ocular melanoma liver metastases. Based on the research conducted in 2016, 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 hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (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 40,710 new cases of these cancers were expected to be diagnosed in the United States in 2017.

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. 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 patient 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

CHEMOSAT and Melphalan/HDS administer concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (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 CHEMOSAT and Melphalan/HDS is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included with the system. 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 toxic side effects and certain risks, some of which are potentially life threatening. An integrated safety population comprised of patients treated during our prior clinical development using early versions of the Melphalan/HDS showed these risks to include grade 3 or 4 bone marrow suppression and febrile neutropenia, as well as risks of hepatic injury, severe hemorrhage, gastrointestinal perforation, stroke, and myocardial infarction in the setting of an incomplete cardiac risk assessment. Deaths due to certain adverse reactions within this integrated safety population were not observed to occur again during the clinical trials following the adoption of related protocol amendments.

Procedure and Product Refinements

The trials that comprised this integrated safety population used early versions of the device and procedure. As a consequence of these identified risks and experience gained in non-clinical, commercial usage in Europe, we have continued to develop and refine both the CHEMOSAT and Melphalan/HDS and the PHP procedure. The procedure refinements have included modifications to the pre, peri and post procedure patient management and monitoring, as well as the use of the following: prophylactic administration of proton pump inhibitors, prophylactic platelet transfusions, prophylactic hydration at key pre-treatment intervals, use of vasopressor agents coupled with continuous monitoring for maintenance of blood pressure and prophylactic administration of growth factors to reduce risk of serious myelosuppression. In addition, in 2012 we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other product enhancements.

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2017, physicians in Europe and the United States also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

Phase 3—Melanoma Metastases Trial

In February 2010, we concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melphalan/HDS, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately four to eight week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, we announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan/HDS for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study’s primary endpoint of extended hepatic progression-free survival (hPFS). An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization and the European Society of Medical Oncology in September 2011. Data submitted in October 2012 to the FDA in Delcath’s New Drug Application (NDA) comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the PHP arm had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the BAC control group, according to the Independent Review Committee (IRC) assessment. This reflects a 4-fold increase of hPFS over that of the BAC arm, with 50% reduction in the risk of progression and/or death in the PHP treatment arm compared to the BAC control arm. Results of this study were published in Annals of Surgical Oncology, in December 2015.

Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

Also, in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using an early version of the Melphalan/HDS in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine

tumors (carcinoid and pancreatic islet cell tumors), ocular or cutaneous melanoma, metastatic colorectal adenocarcinoma (mCRC), and HCC. In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 42%, with 66% of patients achieving hepatic tumor shrinkage and durable disease stabilization. In the mCRC cohort, there was inconclusive efficacy possibly due to advanced disease status of the patients. Similar safety profiles were seen across all tumor types studied in the trial.

Phase 2 Multi-Histology Clinical Trial - HCC Cohort

In the HCC cohort (n=8) of our Phase 2 Multi-Histology trial, a positive signal in hepatic malignancies was observed in 5 patients. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hPFS ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and OS in this limited number of patients exceeded that generally associated with this patient population.

Prior United States Regulatory Experience

Based on the results from our prior clinical development in August 2012, we submitted an 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, and subsequently amended the indication to ocular melanoma metastatic to the liver. Data submitted to the Food and Drug Administration (FDA) used the early clinical trial versions of the system along with early clinical procedure techniques. Our NDA was accepted for filing by the FDA on October 15, 2012 and was designated for standard review with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

On May 2, 2013 we announced that an Oncologic Drug Advisory Committee (ODAC) panel convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of Melphalan/HDS did not outweigh the risks associated with the procedure. A significant portion of FDA’s presentation to the ODAC panel was focused on the FDA’s assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension (low blood pressure) during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression. We believe that the protocol amendments and other procedure refinements instituted during clinical trials and subsequently in commercial, non-clinical usage in Europe, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials in our current CDP.

Briefing materials presented to the 2013 ODAC panel by both the FDA and Delcath are available on our website at http://delcath.com/clinical-bibliography.

2013 Complete Response Letter

In September 2013 the FDA issued a complete response letter (CRL) in response to our NDA. The FDA issues a CRL after the review of a file has been completed and questions remain that preclude approval of the NDA in its current form. The FDA comments included, but were not limited to, a statement that Delcath must perform another "well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks." The FDA also required that the additional clinical trial(s) be conducted using the product the Company intends to market, and that certain clinical, clinical pharmacology, human factors and product quality elements of the CRL be addressed.

In January 2016, we announced the conclusion of a Special Protocol Assessment (SPA) with the FDA on the design of a new Phase 3 clinical trial of Melphalan/HDS to treat patients with hepatic dominant ocular melanoma. This SPA provides agreement that our new Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the entire data in the application. The SPA agreement also represents the satisfactory resolution of a substantial number of the FDA’s CRL non-clinical trial related requirements in that without these successful resolutions, the SPA request would not have been permitted to be filed.

Current Clinical Development Program

The focus of our current 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 procedure have addressed the severe toxicity and procedure-related risks observed during the previous Phase 2 and 3 clinical trials. The 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 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 entitled 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 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 inhibit enrollment in this trial under its previous protocol. With this amendment, we have taken a significant step that we believe will accelerate our timeline to complete trial enrollment while providing a strong scientific case to support an application for approval. With this amendment, we expect to complete enrollment in this trial by the end of the first half of 2019.

The amendment invalidates 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.

In September 2018, we announced that that the independent Data Safety Monitoring Board (DSMB) for this trial completed another review of safety data for treated patients in the trial under the prior protocol. The DSMB has again recommended that the study continue without modification. The trial amendment does not change safety related procedures or invalidate prior DSMB evaluations.

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 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.

Melphalan hydrochloride has been granted orphan drug status by FDA for treatment of patients with ocular melanoma. Based on the strength of the efficacy data in this disease observed in our prior Phase 3 clinical trial and the reports of an improved safety profile observed in non-clinical trial experience in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL. 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.

Percutaneous Hepatic Perfusion (PHP) vs. Cisplatin/Gemcitabine in Patients with Intrahepatic Cholangiocarcinoma - NCT03086993

In April 2018 we announced the initiation of a new pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma (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), overall response rate (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 is now closed to enrollment.

Protocol 202 NCT02415036 – Conducted in Europe, this trial is 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 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 is being 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.

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 (KOL) at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP® therapy does, indeed, "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 entitled 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 available in the Recent Data section of this report.

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 included in Item 8 of its Annual Report on Form 10-K.

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 Investigator Initiated Trial (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 non-randomized, 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 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 October 2018, we announced that results of a multicenter analysis of outcomes in patients with intrahepatic cholangiocarcinoma (ICC) treated with CHEMOSAT were published in the journal European Radiology. The study is the first analysis on the use of Delcath's PHP® Therapy for the treatment of ICC. The retrospective analysis—Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival—was conducted by investigators in Germany, Italy, Netherlands, Spain and France with Dr. Steffen Marquardt of Hannover Medical School serving as lead author. The study evaluated 15 patients with ICC who were selected for PHP treatment after failing prior therapies. The patients were treated at nine hospitals throughout Europe between 2012 and 2016. Treatment outcomes were assessed by imaging every three months following PHP treatment.

Results of the study showed that after the first PHP treatment, one patient (7%) has a complete response (CR), two patients (13%) had a partial response (PR), and stable disease (SD) was observed in eight patients (53%). This equates to a control rate (CR+PR+SD) of 73%. The complete response patient was not retreated and is still alive. Three patients (20%) progressed after the first treatment and one patient died prior to post-procedure imaging. Five of the patients with SD received a second PHP treatment, resulting in one PR (20%), three SD (60%), and one PD (20%). During the follow-up phase two of the SD patients received additional PHP treatments. Median overall survival (OS) was 26.9 months from initial diagnosis and 7.6 months from first PHP treatment. One-year OS from first PHP was 40%. Median progression free survival (PFS) was 122 days, and median hepatic progression free survival (hPFS) was 131 days.

In their retrospective data collection, investigators stated that side-effects were potentially under-reported but were considered by the investigators to be tolerable and comparable to other systemic and local therapies. Nevertheless, in the context of the patient selection, baseline characteristics and number of PHP treatments provided in this retrospective study, practitioners observed no adverse events of grades 3 or 4 severity during the PHP procedure. Post-procedurally, significant hematological toxicity was observed in the form of anemia and thrombocytopenia 5-7 days after the PHP procedure. Management with Granulocyte Colony Stimulating Factor (GCSF) was employed in some patients. These toxicities were considered consistent with those toxicities reported in the ABC 02 trial of systemic chemotherapy in this patient population.

Investigators concluded that PHP Therapy provides "promising response rates in patients with ICC," and that side-effects were tolerable and comparable to other treatment strategies.

In September 2018, we announced the results of two studies presented as posters at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) annual meeting.

One study—Percutaneous Hepatic Perfusion in Patients with Unresectable Liver Metastases from Ocular Melanoma using Delcath Systems' Second Generation (GEN 2) Hemofiltration System: A Prospective Phase 2 Study—was conducted by researchers at LUMC reported by T.S. Meijer, MD. The study prospectively evaluated tumor response rate, safety, overall survival (OS), overall progression-free survival (PFS) and hepatic progression-free survival (hPFS) in 35 patients with ocular melanoma liver metastases treated at LUMC from February 2014 to June 2017. In accordance with the study's protocol, patients were treated with a maximum of two cycles of PHP Therapy and a total 67 PHP treatments were administered to the 35 patients in the study.

Post-treatment assessments were possible in 32 patients. Results of the study, according to RECIST 1.1, showed that a complete response was observed in one patient (3.1%) and a partial response was observed in 21 patients (65.6%), resulting in an objective response rate of 68.7%. Stable disease was observed in four patients (12.5%), for a total disease control rate of 81.2%. Median OS was 15.6 months, median PFS was 8.6 months, and median hPFS was 10.8 months.

In their safety analysis, the researchers reported a total of 14 serious adverse events, including one case of cardiac ischemia, five cases of prolonged hospital admission to treat peri-procedure complications, and eight patients re-hospitalized for a variety of post-procedure symptoms. No deaths occurred on the study. No severe bleeding complications, myocardial or cerebral infarctions were observed. Hematologic toxicities of Grade 3/4 were observed in most patients, with 18 (54.5%) patients experiencing thrombocytopenia and 22 patients (66.7%) experiencing neutropenia. The researchers stated that hematologic events were manageable or self-limiting. Additionally, no grade 3 or 4 hepatic serious adverse events were observed by the researchers. The LUMC investigators concluded that, in their institution's study, PHP Therapy was shown to have a manageable adverse event profile and to be a potentially valuable treatment for certain patients with ocular melanoma liver metastases.

Another study entitled Survival and Response of Patients with Metastatic Ocular Melanoma after Chemosaturation Percutaneous Hepatic Perfusion was conducted by M. Zeile, and A. Stang, et al of the Asklepios Barmbek Clinic in Hamburg, Germany. The study retrospectively evaluated response rates and overall survival in 12 patients with ocular melanoma liver metastases after treatment with Delcath's PHP® Therapy. Five patients had metastases confined to the liver, and seven had additional extra-hepatic metastases. A total of 30 PHP procedures were performed in the sample, and patients received an average of 2.5 treatments.

Results of the study showed the objective response rate (ORR) was 58.3%, and the disease control rate was 91.7% (1 complete response, 6 partial responses, 4 stable disease, and 1 progressive disease). Following the first PHP treatment, progression free survival was 11.7 months and hepatic progression free survival (hPFS) was 18.6 months. Median

overall survival (OS) was 30.6 months following the treatment. Of the cohort of 12 patients, three patients were judged to be candidates for surgery following treatment with PHP. Median OS among these patients was 76.8 months, though investigators cautioned that statistical conclusions cannot be drawn from the small sample size.

In May 2018 we announced that PHP Therapy was featured in a Video Learning Session presented at the Annual Meeting of the European Conference of Interventional Oncology (ECIO). Dr. M.C. Burgmans of Leiden University Medical Center (LUMC) in the Netherlands presented the training in the main auditorium session dedicated to advances in liver cancer therapies. Dr. Burgmans presented an overview of the Percutaneous Hepatic Perfusion (PHP) procedure, discussed the therapy's developmental history, demonstrating how to perform the procedure, as well as outlining its potential in ocular melanoma liver metastases and intrahepatic cholangiocarcinoma, and highlighting ongoing clinical research.

In his presentation, Dr. Burgmans stated his belief that PHP Therapy should be considered as first line therapy in ocular melanoma liver metastases, an opinion informed by both our commercial experience in Europe and our prior research into this tumor type. LUMC is an experienced treatment centers, and has recently completed its 100th treatment using CHEMOSAT. We believe Dr. Burgmans comments reflect growing confidence in this therapy's role in treating ocular melanoma liver metastases.

Market Access and Commercial Clinical Adoption

Europe

Our market access and clinical adoptions efforts are focused on the key target markets of Germany, United Kingdom and the Netherlands, which represent a majority of the total potential liver cancer market (primary and metastatic) in the Europe and where progress in securing reimbursement for CHEMOSAT treatments offers the best near-term opportunities. We also continue to support clinical adoption of CHEMOSAT in Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since launching CHEMOSAT in Europe, over 600 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. In 2017, SPIRE Southampton Hospital in the U.K. and the Medical University of Hannover in Germany each surpassed 100 treatments with CHEMOSAT since initiating procedures and in 2018, Leiden University Medical Centre in the Netherlands surpassed 100 treatments with CHEMOSAT since initiating procedures.

In March 2018, we announced that we entered into a commercial supply agreement with Tillomed Laboratories, an EMCURE company, for the procurement of melphalan for use with CHEMOSAT in Europe. Tillomed Laboratories specializes in the licensing, marketing and supply of generic and branded pharmaceutical products to hospitals, wholesalers and pharmacists nationwide, in a cost-effective and timely manner. We believe this agreement establishes firm control over our melphalan supply chain in Europe, and over time will provide economies of scale. The supply agreement with Tillomed also gives Delcath access to the drug dossier for melphalan hydrochloride, an important asset that potentially provides a drug approval pathway with the European Medicines Agency (EMA) in Europe. As many of the cancers of the liver we are treating with CHEMOSAT are orphan indications in the United States, a Marketing Authorization Application (MAA) approval by the EMA for CHEMOSAT could potentially provide added market protection for these indications 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.

Germany

In October 2015, we announced that the Institut f r 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, 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 the National Institute for Clinical Excellence (NICE) in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. This would enable greater scope for commercialization because it would allow more use by NHS clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement with 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.

Spain

In Spain, the Company has determined that there was no benefit to continuing with its relationship with a local sales agency and has exited the Spanish market.

Turkey

In April 2016 we announced the activation of the Hacettepe University Clinic in Ankara, Turkey as a CHEMOSAT treatment center. Hacettepe University Clinic successfully completed its first CHEMOSAT treatments in March 2016, and the center represents the first CHEMOSAT commercial location to be activated outside of the European Union. In 2018 a second center has been activated in Turkey. We believe that these centers can serve as important location for CHEMOSAT treatment to patients in Turkey and throughout the region.

Distribution Partners

As a result of the Company’s strategy to prioritize resources on the key direct markets of Germany, the Netherlands and the United Kingdom, the Company expects that its distribution strategy will play a lesser role in its current

commercial activities. The Company is represented in Turkey through a distribution partner.

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 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 (EEA) 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.

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.

Patents Issued in the United States

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

Patent Applications in the United States

Application No.	Application Title	Filing Date	Owned or Licensed
15/071,896	Filter and Frame Apparatus and Method of Use	3/16/2016	Owned
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/8/2016	Owned
16/127,008	Apparatus For Removing Chemotherapy Compounds from Blood	9/10/2018	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
2797644	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

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 European Union 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 and expect that we will not need a third party representative in the future.

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

The CHEMOSAT device has received registrations in the following countries: Australia, New Zealand, Argentina, Taiwan, and Singapore. With limited resources and our attention focused on European commercial and clinical

adoption efforts, pursuing other markets at this time is not practical. We will continue to evaluate commercial opportunities in these and other 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.

The 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 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 intend to conduct final manufacturing and assembly in the future. 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 facilties are presently ISO 13485:2016 certified.

Recent Events

In July 2018, the Company entered into a Securities Purchase Agreement (the "July 2018 SPA") with an institutional investor for the remaining Notes and Warrants in proportionate amounts to those issued in the June 2018 transaction. July 2018 Notes in the amount of $2.2 million and July 2018 Pre-Funded Series D Warrants in the amount of $0.1 million were issued for cash proceeds of $1.6 million with an original issue discount in the amount of $0.7 million. Of the $2.2 million in issued July 2018 Notes, $1.6 million matures in six months; the balance of $0.6 million is payable in twelve installments beginning seven months after the original issuance date. At issuance, the July 2018 Series D Warrant was exercisable to acquire 0.8 million shares of Common Stock at an initial exercise price of $4.00 and the July 2018 Pre-Funded Series D Warrants were exercisable to acquire 9.2 million shares of common stock at a pre-funded exercise price of $0.01.

In July 2018, the Company and the investor from the June 2018 transaction amended the June 2018 Pre-Funded Series D Warrants so that they are exercisable as of July 20, 2018 and the Company may redeem them at any time the Notes are no longer outstanding and the Company is not in default. The Company and the investor from the June 2018 transaction also amended the definition of a Fundamental Transaction in the June 2018 Series D Warrants. This amendment resulted in the June 2018 Series D Warrants being reclassified from a liability to equity.

In August 2018, the Company entered into an agreement to sell up to $6.0 million purchase price of its 8% Senior Secured Convertible Notes and Series D Warrants and Series D Pre-Funded Warrants pursuant to a Securities Purchase Agreement with one or more institutional investors. The Agreement has substantially the same terms as the June 2018 SPA and July 2018 SPA, except that the conversion price under the Notes and exercise price of the Warrants is $1.75, and interest on the Notes shall accrue and be payable at maturity. Notes in the amount of $3.3 million (the "August 2018 Notes") and August 2018 Pre-Funded Series D Warrants in the amount of $0.2 million were issued for cash proceeds of $2.5 million with an original issue discount in the amount of $1.1 million. Of the $3.3 million in issued August 2018 Notes, $2.5 million matures in six months; the balance of $0.8 million is payable in twelve installments beginning seven months after the original issuance date. At issuance, the August 2018 Series D Warrant was exercisable to acquire 2.0 million shares of common stock at an initial exercise price of $1.75 and the August 2018 Pre-Funded Series D Warrants were exercisable to acquire 23.8 million shares of common stock at a pre-funded exercise price of $0.01.

In August 2018, the Company amended its June 2018 Notes and July 2018 Notes such that the conversion price was reduced to $1.75, interest shall accrue until maturity, and the first $2.5 million and 50% of any subsequent financings shall be used to satisfy the Company's obligations under the Notes. Effective the same date, the Company also amended its Pre-Funded Warrants such that the total number of June 2018 Pre-Funded Warrants was increased from 13.0 million to 22.2 million and the total number of July 2018 Pre-Funded Warrants was increased from 9.2 million to 15.8 million.

In September 2018, the Company entered into a SPA with another institutional investor for a remaining portion of the August 2018 Notes and Warrants. September 2018 Notes in the amount of $0.5 million and September 2018 Pre-Funded Warrants in the amount of $0.03 million were issued for cash proceeds of $0.4 million with an original issue discount in the amount of $0.2 million. Of the $0.5 million in issued September 2018 Notes, $0.4 million matures in six months; the balance of $0.1 million is payable in twelve installments beginning seven months after the original issuance date. At issuance, the September 2018 Series D Warrant was exercisable to acquire 0.3 million shares of common stock at an initial exercise price of $1.75 and the September 2018 Pre-Funded Warrants were exercisable to acquire 3.1 million shares of common stock at a pre-funded exercise price of $0.01.

All of the Notes between June 2018 and September 2018 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.

On September 27, 2018 we announced the closing of the subscription period of for our previously announced rights offering. The rights offering was made pursuant to a Registration Statement on Form S-1 that was made effective on August 3, 2018. At the end of the subscription period on September 26, 2018, Delcath had received 4,249,604 basic subscriptions and 418,207 oversubscriptions for a total of 4,667,811 subscriptions, each subscription for one share of its Common Stock. Gross proceeds from the offering were $8.2 million, and net proceeds were approximately $7.0

million.

Pursuant to the Amendment to the June 2018 and July 2018 Notes discussed above, the Company repaid $4.9 million in outstanding Notes during the first week of October 2018.

Results of Operations for the three and nine months ended September 30, 2018; Comparisons of Results of Operations for the three and nine months ended September 30, 2018

Three months ended September 30, 2018 and September 30, 2017

Revenue

The Company recorded approximately $0.8 million in revenue related to product sales for the three months ended September 30, 2018 and $0.7 million in revenue related to product sales for the three months ended September 30, 2017. Although sales remain modest, the increase is driven by the establishment of ZE diagnostic-related group reimbursement for CHEMOSAT procedures in Germany.

Cost of Goods Sold

For the three months ended September 30, 2018, the Company recorded cost of goods sold of approximately $0.2 million compared to $0.2 million for the three months ended September 30, 2017.

Selling, General and Administrative Expenses

For the three month period ended September 30, 2018 and 2017, selling, general and administrative expenses were $2.3 million and $2.9 million, respectively. The decrease for the three months ended September 30, 2018 is primarily related to costs associated with the Company’s shareholder meetings held in 2017 that were not incurred in 2018 and a reduction in independent audit fees due to testing the Company’s internal control over financial reporting in 2017 that is not required in 2018.

Research and Development Expenses

For the three month period ended September 30, 2018 and 2017, research and development expenses increased to $4.1 million from $2.3 million, primarily due to the ongoing accrual of the Company’s Phase 3 FOCUS trial which is discussed in further detail in the Current Clinical Development Program section above.

Other Income/Expense and Interest Income/Expense

Other expense is primarily related to foreign currency exchange gains and losses.

Interest expense is related to:

1. the restructuring lease liability discussed in Note 7 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q; and
2. the amortization of debt discounts discussed in Note 8 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

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

Change in the fair value of the warrant liability

For the three months ended September 30, 2018 the change in the fair value of the warrant liability increased to income of $1.2 million versus $0.03 million for the three months ended September 30, 2017. The increase of $1.2 million is due to the mark-to-market adjustments to the 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.

Net Loss

The Company recorded a net loss for the three months ended September 30, 2018, of $8.9 million, a decrease of $3.7 million, or 29.5%, compared to a net loss of $12.6 million for the same period in 2017. This decrease in net loss is primarily due to a $1.9 million decrease in interest expense, a $1.8 million reduction in loss on debt extinguishment and a $1.2 million increase in the change in the fair value of the warrant liability, all non-cash items. This decrease was slightly offset by a $1.2 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Nine months ended September 30, 2018 and September 30, 2017

Revenue

The Company recorded approximately $2.4 million in revenue related to product sales for the nine months ended September 30, 2018 and $2.0 million in revenue related to product sales for the nine months ended September 30, 2017. Although sales remain modest, the increase is driven by the establishment of ZE diagnostic-related group reimbursement for CHEMOSAT procedures in Germany.

Cost of Goods Sold

For the nine months ended September 30, 2018, the Company recorded cost of goods sold of approximately $0.6 million compared to $0.5 million for the nine months ended September 30, 2017.

Selling, General and Administrative Expenses

For the nine months ended September 30, 2018 the Company recorded selling, general and administrative expenses of approximately $7.3 million compared to $7.8 million for the nine months ended September 30, 2017. The decrease for the nine months ended September 30, 2018 is primarily related to costs associated with the Company’s shareholder meetings held in 2017 that were not incurred in 2018 and a reduction in independent audit fees due to testing the Company’s internal control over financial reporting in 2017 that is not required in 2018.

Research and Development Expenses

For the nine months ended September 30, 2018 and 2017, research and development expenses increased to $13.9 million from $7.1 million, primarily due to the ongoing enrollment of our Phase 3 trial during 2018 which is discussed in further detail in the Current Clinical Development Program section above.

Other Income/Expense and Interest Expense

Other expense is primarily related to foreign currency exchange gains and losses.

Interest expense is related to:

1. the restructuring lease liability discussed in Note 7 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q; and
2. the amortization of debt discounts discussed in Note 8 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

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

Change in the fair value of the warrant liability

For the nine months ended September 30, 2018 the change in the fair value of the warrant liability increased to income of $18.4 million from $1.2 million for the nine months ended September 30, 2017. The increase of $17.2 million is due to the extinguishment of the Series C Warrants during the nine months ended September 30, 2017 and the mark-to-market adjustments to the 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.

Net Loss

The Company recorded net loss for the nine months ended September 30, 2018 of $8.4 million, a decrease of $17.5 million, or 67.7%, compared to a net loss of $25.9 million for the same period in 2017. This decrease in net loss is primarily related to a $0.3 million increase in gross profit and a $23.4 million decrease in various non-cash items, including interest expense related to the amortization of debt discounts, gains related to the extinguishment of the June 2016 Series C Warrants and the change in the fair value of the warrant liability. This decrease was offset by a $6.2 million increase in operating expenses driven by an increased investment in our clinical trial initiatives.

Liquidity and Capital Resources

The Company's capital resources as of September 30, 2018 are not sufficient to fund planned operations during 2018. 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. 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 September 30, 2018, the Company had cash, cash equivalents and restricted cash totaling $10.0 million, as compared to cash, cash equivalents and restricted cash totaling $5.3 million at December 31, 2017 and $10.9 million at September 30, 2017. During the nine months ended September 30, 2018 and September 30, 2017, the Company used $12.9 million and $11.7 million respectively, of cash in its operating activities. Including the $850,000 raised in November 2018 through the issuance of Series D Preferred Shares, the Company believes that its capital resources are adequate to fund its operating activities into December 2018.

Our consolidated financial statements as of September 30, 2018 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 of its securities, and public offerings in 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016 and 2018, 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. For a detailed discussion of the Company's various sales of securities see Note 9 to the Company's financial statements contained in this Quarterly Report on Form 10-Q.

In October 2018, the Company filed a registration statement on Form S-3 with the SEC. Once declared effective by the SEC, the Form S-3 will allow 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, and debt securities as it deems prudent or necessary to raise capital at a later date.

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 financial statements contained in the 2017 Annual Report on Form 10-K.

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 September 30, 2018, the February 2018 Warrants had an exercise price of $10.00 per share with 1.0 million 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 2013 Warrants, February 2015 Warrants, the July 2015 Series A Warrants, the October 2016 Warrants, the November 2017 Warrants, the February 2018 Warrants and the June 2018 Series D Warrants (the "Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As discussed in Note 8, the Series D Warrants were subsequently reclassified to equity. For the nine months ended September 30, 2018, the Company recorded pre-tax derivative instrument income of $1.2 million. The fair value of the Warrants totaled $1.5 million at September 30, 2018. Management expects that the warrants outstanding at September 30, 2018 will either be exercised or expire worthless. The fair value of the Warrants at September 30, 2018 was determined by using option pricing models assuming the following:

	September 30, 2018	December 31, 2017
Expected life (in years)	0.08 - 5.36	0.82 - 4.88
Expected volatility	139.47% - 258.34%	130.88% - 266.92%
Risk-free interest rates	2.12% - 2.97%	1.68% - 2.06%

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 September 30, 2018 (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 September 30, 2018 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

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the "Suit"). The Suit alleges breaches by the Company of Hudson Bay's rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. The Company denies any liability with respect to the claims set forth in the Suit.

Item 1A. Risk Factors

Delcath's 2017 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.

We have had a legal proceeding filed against us, and it is premature to assess what the potential outcome of the proceeding will be, and what impact, if any, the outcome could have on our business.

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the "Suit"). The Suit alleges breaches by the Company of Hudson Bay's rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. While the Company denies any liability with respect to the claims set forth in the Suit, it is premature to assess the outcome of this proceeding, and what, if any, impact any potential outcome could have on our business operations or financial condition.

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

On June 4, 2018 the Company sold 8% Senior Secured Convertible Promissory Notes ("Notes") and warrants and prepaid warrants ("Warrants") pursuant to a Securities Purchase Agreement ("Agreement") with an institutional investor in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), Regulation S and Rule 506(b) promulgated thereunder, and received gross proceeds of $2,400,000. The Agreement provided for an aggregate subscription amount for all securities to all purchasers of up to $4,000,000. On July 20, 2018, the Company entered into a second Securities Purchase Agreement with another institutional investor for the remaining Notes and Warrants in proportionate amounts to those issued in the June 4, 2018 transaction, in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act and Rule 506(b) promulgated thereunder, and received gross proceeds of $1,600,000.

On August 31, 2018 the Company sold 8% Senior Secured Convertible Promissory Notes ("Notes") and warrants and prepaid warrants ("Warrants") pursuant to a Securities Purchase Agreement ("Agreement") with an institutional investor in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), Regulation S and Rule 506(b) promulgated thereunder, and received gross proceeds of $2,500,000. The Agreement provided for an aggregate subscription amount for all securities to all purchasers of up to $6,000,000. On September 21, 2018, the Company entered into a second Securities Purchase Agreement with another institutional investor for a portion of the remaining Notes and Warrants and received gross proceeds of $350,000.

Item 3. Defaults upon Senior Securities
None.

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.

November 13, 2018 DELCATH SYSTEMS, INC.
(Registrant)

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