DELCATH SYSTEMS, INC.
Form 10-Q
August 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

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

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	(Do not check if a smaller reporting company)	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 7(a)(2)(B) of the Securities Act .

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

As of August 7, 2017, 499,031,259 shares of the Company’s common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 1,816	$4,409
Restricted cash	12,861	27,287
Accounts receivables, net	384	403
Inventories	1,040	660
Prepaid expenses and other current assets	499	698
Deferred financing costs	771	699
Total current assets	17,371	34,156
Property, plant and equipment, net	1,232	1,083
Total assets	$ 18,603	$35,239
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 990	$594
Accrued expenses	3,579	3,407
Convertible notes payable, net of debt discount	12,598	13,343
Warrant liability	43	18,751
Total current liabilities	17,210	36,095
Deferred revenue	32	30
Other non-current liabilities	494	604
Total liabilities	17,736	36,729
Commitments and Contingencies	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	—	—
Common stock, $.01 par value; 500,000,000 shares authorized; 424,526,067 and 4,131,527 shares issued and 424,408,256 and 4,112,417 shares outstanding at June 30, 2017 and December 31, 2016, respectively*	4,245	41
Additional paid-in capital	289,186	277,749
Accumulated deficit	(292,464)	(279,188)
Treasury stock, at cost; 110 shares at June 30, 2017 and December 31, 2016,	(51)	(51)

respectively*		
Accumulated other comprehensive income	(49)	(41)
Total stockholders' equity (deficit)	867	(1,490)
Total liabilities and stockholders' equity (deficit)	$ 18,603	$ 35,239

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Revenue	$584	$511	$1,327	$880
Cost of goods sold	135	150	354	261
Gross profit	449	361	973	619
Operating expenses:				
Selling, general and administrative	2,532	2,287	4,947	4,663
Research and development	2,518	1,945	4,840	3,289
Total operating expenses	5,050	4,232	9,787	7,952
Operating loss	(4,601)	(3,871)	(8,814)	(7,333)
Change in fair value of the warrant liability, net	(38)	(1,181)	1,200	491
Gain on warrant extinguishment	9,613	—	9,613	—
Interest expense	(6,916)	(1,614)	(15,282)	(1,631)
Other income (expense)	(1)	(1)	7	(7)
Net loss	$(1,943)	$(6,667)	$(13,276)	$(8,480)
Other comprehensive loss:				
Foreign currency translation adjustments	(30)	(1)	(8)	(10)
Comprehensive loss	$(1,973)	$(6,668)	$(13,284)	$(8,490)
Common share data:				
Basic loss per share*	$(0.01)	$(4.41)	$(0.09)	$(5.72)
Diluted loss per share*	$(0.01)	$(4.41)	$(0.09)	$(5.72)
Weighted average number of basic common shares outstanding*	252,264,959	1,510,752	148,674,658	1,483,148
Weighted average number of diluted common shares outstanding*	252,264,959	1,510,752	148,722,094	1,483,148

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)

(Unaudited)

(in thousands, except share data)

	Common Stock Issued $0.01 Par Value		Treasury Stock				Accumulated Other	
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Comprehensive loss	Total
Balance at January 1, 2017	4,131,527	$41	(110)	$ (51)	$ 277,749	$ (279,188)	$ (41)	$ (1,490)
Compensation expense for issuance of stock options	—	—	—	—	46	—	—	46
Compensation expense for issuance of restricted stock	91,344	1	—	—	63	—	—	64
Issuance of common stock for payments made in shares on convertible note payable	420,199,367	4,202	—	—	11,296	—	—	15,498
Warrants Exercised	103,829	1	—	—	13	—	—	14
Fair value of warrants exercised	—	—	—	—	19	—	—	19
Net loss	—	—	—	—	—	(13,276)	—	(13,276)
Total comprehensive loss	—	—	—	—	—	—	(8)	(8)
Balance at June 30, 2017	424,526,067	$4,245	(110)	$ (51)	$ 289,186	$ (292,464)	$ (49)	$867

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Six months ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(13,276)	$(8,480)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	46	114
Restricted stock compensation expense	64	190
Depreciation expense	127	169
Loss on disposal of equipment	20	1
Warrant liability fair value adjustment	(1,200)	(491)
Gain on warrant extinguishment	(9,613)	-
Non-cash interest income	(1)	(2)
Deferred revenue	2	19
Debt discount and deferred finance costs amortization	15,277	1,568
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	201	170
Increase in accounts receivable	(94)	(94)
Decrease (increase) in inventories	(208)	14
Increase (decrease) in accounts payable and accrued expenses	628	(42)
Decrease in other non-current liabilities	(110)	(104)
Net cash used in operating activities	(8,137)	(6,968)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(276)	(95)
Increase in restricted cash		(1,062)
Net cash used in investing activities	(276)	(1,157)
Cash flows from financing activities:		
Increase in restricted cash	-	(29,200)
Net proceeds from the release of restricted cash	5,954	-
Release of restricted cash for extinguishment of Series C Warrants	7,876	-
Extinguishment of Series C Warrants	(7,876)	-
Net proceeds from convertible debt financing	-	31,523
Net proceeds from sale of stock and exercise of warrants	15	704
Net cash provided by financing activities	5,969	3,027
Foreign currency effects on cash and cash equivalents	(149)	(25)

Net decrease in cash and cash equivalents	(2,593)	(5,123)
Cash and cash equivalents:		
Beginning of period	4,409	4,409
End of period	$1,816	$1,818
Supplemental non-cash activities:		
Conversion of convertible notes	$15,831	$—
Fair value of warrants issued	$—	$28,133
Fair value of warrants exercised	$19	$245

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

(1) General

The interim condensed consolidated financial statements of Delcath Systems, Inc. ("Delcath" or the "Company") as of and for the three and six months ended June 30, 2017 and 2016 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, 2016 ("Annual Report"), which has been filed with the Securities Exchange Commission ("SEC"), , as amended by that certain Amendment No. 1 to Form 10-K for the year ended December 31, 2016, filed with the SEC on July 14, 2017 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 in commercial development 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 for CHEMOSAT/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 overall survival in mOM, and a registration trial for intrahepatic cholangiocarcinoma (ICC) we plan to initiate in the fall of 2017. Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC).

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 has an accumulated deficit of $292.5 million at June 30, 2017. As shown in the accompanying financial statements during the three and six months ended June 30, 2017, the Company incurred net losses of $1.9 million and $13.3 million, respectively and during the six months ended June 30, 2017 used $8.1 million of cash for its operating activities. These factors among others raise 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.

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. As a result of issuing $35.0 million in senior secured convertible notes in June 2016 and assuming the Company is able to effect a reverse stock split as proposed in its recent consent solicitation statement filed with the SEC on July 26, 2017, management believes that its capital resources are adequate to fund operations through the end of 2017. To the extent additional capital is not available when needed, 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 the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainties and risks related to clinical research, product development; regulatory approvals; technology; patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing; marketing and sales experience; and dependence on key personnel.

On July 26, 2017 the Company filed a Definitive Schedule 14A detailing a proposed reverse stock split, subject to shareholder approval. To continue to fund our operations and support our clinical programs, we need the ability to issue common shares, both to service the amortization of the above referenced convertible note and to explore alternative equity financing. However, we are currently at the threshold of the Authorized Shares limit in our Certificate of Incorporation. Without a sufficient number of authorized shares, we are unable to access the $11.8 million of cash in the restricted accounts associated with those convertible notes issued last year, or to undertake any type of equity fund raise. The proposed reverse split of our common shares will reduce the shares outstanding and provide us with the flexibility to raise equity capital and support our important clinical trials and our commercial efforts in Europe.

Effecting the reverse stock split will also allow Delcath to remain in compliance with NASDAQ Capital Market exchange stock listing requirements, which provides liquidity and other important benefits to the Company and its investors. It is important to note that the floor price for the Convertible Note will adjust with the effected reverse stock split ratio to a minimum of $1.00. We believe this should serve to support the stock price following a split and reduce future potential dilution related to the convertible note.

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 June 30, 2017 and 2016; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 Summary of Significant Accounting Policies to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K filed for the period ended December 31, 2016.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 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. ASU 2014-09 is effective for the Company beginning in its fiscal year 2018, and may be applied retrospectively to all prior periods presented or through a cumulative adjustment to the opening retained earnings balance in the year of adoption. The Company intends to adopt this standard on January 1, 2018 and does not anticipate that this guidance will materially impact its consolidated financial statements.

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 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 Company is currently evaluating the effects, if any, that the adoption of this guidance will have on the Company’s financial statements.

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 intends to adopt this standard on January 1, 2018 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company's financial statements.

(2) Inventories

Inventories consist of the following:

(in thousands)	June 30, 2017	December 31, 2016
Raw materials	$301	$ 346
Work-in-process	560	214
Finished goods	179	100
Total inventories	$1,040	$ 660

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	June 30, 2017	December 31, 2016
Insurance premiums	$252	$ 501
Security Deposit	50	50
Other[1]	197	147
Total prepaid expenses and other current assets	$499	$ 698

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at June 30, 2017 and December 31, 2016.

(4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	June 30, 2017	December 31, 2016
Buildings and land	$574	$ 556
Enterprise hardware and software	1,647	1,532
Leaseholds	1,621	1,504
Equipment	890	940
Furniture	181	354
Property, plant and equipment, gross	4,913	4,886
Accumulated depreciation	(3,681)	(3,803)
Property, plant and equipment, net	$1,232	$ 1,083

Depreciation expense for the three and six months ended June 30, 2017 was approximately $0.1 million and $0.1 million, respectively, as compared to approximately $0.1 million and $0.2 million, respectively, for the same periods in 2016.

(5) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	June 30, 2017	December 31, 2016
Compensation, excluding taxes	$797	$ 933
Clinical trial expenses	1,348	1,365
Professional fees	256	286
Short-term portion of lease restructuring	221	216
Other[1]	957	607
Total accrued expenses	$3,579	$ 3,407

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at June 30, 2017 and December 31, 2016.

(6) Restructuring Expenses

In order to help reduce operating costs and more appropriately align its office space with the reduced 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. As of June 30, 2017, the total remaining lease restructuring liability for its leased office space was approximately $0.7 million, of which approximately $0.2 million and $0.5 million were included in Accrued expenses and Other non-current liabilities on the condensed consolidated balance sheets, respectively.

The following table provides the year-to-date activity of the Company's restructuring reserves as of June 30, 2017:

(in thousands)	Lease Liability
Reserve balance at December 31, 2016	$ 820
Charges	—
Payments/Utilizations	(104)
Reserve balance at June 30, 2017	$ 716

(7) Convertible Notes Payable

On June 6, 2016, the Company entered into a Securities Purchase Agreement (the "SPA") with certain investors named on the Schedule of Buyers attached to the SPA pursuant to which the Company issued $35.0 million in principal face amount of senior secured convertible notes of the Company (the "Notes") and related Series C Warrants (the "Series C Warrants") to purchase additional shares of the Company's common stock, par value $0.01 per share ("Common Stock"). $35.0 million of the Notes were issued for cash proceeds of $32.2 million with an original issue discount in the amount of $2.8 million. The Notes are secured pursuant to a Security Agreement which creates a first priority security interest in all of the personal property (other than Excluded Collateral (as defined in the Security Agreement) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future.

The Notes do not bear any ordinary interest. However, interest shall commence accruing immediately upon the occurrence of, and shall continue accruing during the continuance of, an Event of Default, at 15% per annum and shall be computed on the basis of a 360-day year of twelve 30-day months and shall be payable, if applicable, in arrears for each calendar month on the first (1st) business day of each calendar month after any such interest accrues after an Event of Default.

Under the terms of the Notes, at closing the Company received an initial tranche of $3.0 million for immediate use for general corporate purposes. A second tranche of $3.0 million was released to the Company in December 2016. An additional $6.6 million was released during the three months ended March 31, 2017. Under the terms of warrant repurchase agreements signed in April 2017 and discussed in more detail below, $7.9 million was returned to the holders in exchange for the extinguishment of the Series C Warrants. The remaining cash proceeds of $11.8 million are being held in restricted accounts. Until the Company can effect a reverse stock split, as proposed in its recent consent solicitation statement filed with the SEC on July 26, 2017, it will not be able to access the $11.8 million of cash held in the restricted accounts.

In connection with the issuance of the Notes under the SPA, the Company also issued Series C Warrants, exercisable to acquire 6.8 million shares of Common Stock. The provisions in the Series C Warrants required the Company to account for the warrants as derivative liabilities. The Company recognized a discount to debt of $27.8 million related to the initial fair value of the Series C Warrants. On April 2, 2017 the Company entered into separate warrant repurchase agreements (the "Warrant Repurchase Agreements") with each of the investors named on the Schedule of Buyers attached to the SPA. Pursuant to the Warrant Repurchase Agreements, each investor agreed to a Controlled Account Release, in an aggregate amount equal to $7.9 million, which funds in each case were paid to the respective investor, in exchange for cancellation of the Warrants issued to each investor under the SPA. As a result of the extinguishment, the Company recognized a gain of $9.6 million, representing the difference between the fair value of the liability as of the extinguishment date of $17.5 million related to the Series C Warrants and the $7.9 million in cash returned to the Noteholders to extinguish the liability.

The Company has agreed to make amortization payments with respect to the Notes in fourteen (14) equal installments beginning seven (7) months after the original date of issuance of June 13, 2016 (each, an "Installment Date"). On each installment date, assuming certain equity conditions are met, the installment payment shall, at the election of the Company, automatically be converted into shares of Common Stock at a conversion rate defined in the agreement. If we cannot meet the equity conditions, we could be required to repay some or all of the amounts due under the notes in cash, and we may not have the funds available to make one or more of such payments when due. At any time after the issuance of the Notes, the Notes will be convertible at the election of the holder into shares of our Common Stock at a conversion price equal to $4.39, subject to adjustment as provided in the Notes. Until the Company can effect a reverse stock split, as proposed in its recent consent solicitation statement filed with the SEC on July 26, 2017, it cannot make amortization payments or conversions.

The Company issued shares of Common Stock as payments of principal (including certain early repayments at the option of the holders) under the Notes as follows:

	Number of Shares of Common Stock	Number of Shares of Preferred Stock	Applicable Conversion Price	Reduction in Principal
January 12, 2017	4,113,520	—	$ 0.36	$1,478,318
January 26 - February 1, 2017[1]	1,700,000	—	$ 0.32	544,000
February 10, 2017	15,358,864	—	$ 0.20	3,045,817
February 23 - March 2, 2017[1]	900,000	—	$ 0.14	126,000
March 13, 2017	41,054,082	—	$ 0.11	4,417,830
April 10, 2017	59,171,335	—	$ 0.06	3,621,286
May 9, 2017	38,278,294	—	$ 0.05	1,913,915
June 7 / July 2, 2017 Exchange Agreement[2]	241,428,571	4,200	—	4,200,000
July 7, 2017	40,000,000	—	$ 0.05	2,000,000
Total	442,004,666			$21,347,166

[1]During the periods referenced above, the Company and the holders of the Notes agreed to a temporary reduction in the conversion price in order to encourage voluntary conversion of Notes by the holders thereof.

[2] On July 2, 2017, we entered into an exchange agreement with one of our investors which had purchased Notes, for $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock. The Series A Preferred Stock shares were issued to address a short-term valuation issue for 241,428,571 common shares delivered

to the Notes holders to close an installment period. Through the Series A Preferred Shares placement, the Company was able to value the open installment shares such that the amount of debt remaining under the Notes was reduced by $4.2 million.

As a result of the Notes including a feature such that the conversion price is based upon a formula which includes discounts to the market price of the common stock as well as having a lower effective conversion price considering the issuance discount and the value allocated to the Series C Warrants, the Company has recognized a beneficial conversion feature of $4.4 million. The original issue discount, the beneficial conversion feature, and the fair value of the issuance of the Series C Warrants are collectively considered the debt discount. The Company recorded a debt discount in the amount of $35.0 million which is being amortized over the life of the Notes using the effective interest method. As of June 30, 2017, $28.7 million of the debt discount has been amortized to interest expense. In addition to the debt discounts listed above, the Notes also include put options in the event of default and change in control as defined in the Notes. The value of such options was zero as the probability for such events was remote as of the issuance date and at June 30, 2017.

All debt issuance costs are accounted for as a deferred asset and will be amortized over the life of the Notes. As of June 30, 2017, the Company had incurred approximately $1.6 million in debt issuance costs and had amortized approximately $0.8 million of those costs.

The following table summarizes the convertible notes outstanding at June 30, 2017:

(in thousands)	
Convertible notes payable, principal	$18,853
Debt discounts	(6,256)
Net convertible note payable	$12,598

(8) Stockholders' Equity
Stock Issuances

Reverse Stock Split

On July 19, 2016, shareholders of the Company approved, through a shareholder vote, an amendment to the Company's Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath's common stock at a ratio within a range of one-for-ten (1:10) to one-for-twenty (1:20). The reverse stock split became effective on July 21, 2016 at which time Delcath's common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen (1:16) split-adjusted basis. All owners of record as of the open of the NASDAQ market on July 21, 2016 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and 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-sixteen 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 interim condensed 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.

In addition, shareholders of the Company also approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 170,000,000 to 500,000,000. The previously discussed reverse stock split had no impact on the increase in authorized shares.

Warrants

In October 2013, the Company completed the sale of 81,875 shares of its common stock and the issuance of warrants to purchase approximately 37,000 common shares (the "2013 Warrants") pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 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. At June 30, 2017, the 2013 Warrants were exercisable at $112.64 per share with approximately 37,000 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 153,750 shares of its common stock and the issuance of warrants to purchase 69,000 common shares (the “February 2015 Warrants”) pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 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. At June 30, 2017, the February 2015 Warrants were exercisable at $0.14 per share with approximately 30,000 warrants outstanding. The February 2015 Warrants have a five-year term.

In July 2015, the Company completed the sale of approximately 0.6 million Units consisting of 0.6 million shares of its common stock, Series A Warrants to purchase up to approximately 0.4 million common shares ("Series A Warrants") and Series B Warrants to purchase Units consisting of up to approximately 0.6 million common shares ("Series B Warrants") and 0.4 million Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the Series A and Series B Warrants. During the three months ended March 31, 2016, approximately 0.1 million Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 0.4 million Series B Warrants expired on January 29, 2016 and the remaining liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 0.1 million Series A Warrants were issued. The exercise price of the Series A Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is 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. At June 30, 2017, the Series A Warrants were exercisable at $0.14 with approximately 0.2 million warrants outstanding. The Series A Warrants have a five-year term. There were approximately 0.1 million July 2015 Series A Warrants exercised during the six months ended June 30, 2017 for proceeds of approximately $15,000.

In October 2016, the Company completed the sale of 425,000 shares of its common stock and the issuance of warrants to purchase 148,750 common shares (the "October 2016 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 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 June 30, 2017, the October 2016 Warrants were exercisable at $0.14 per share with 0.1 million warrants outstanding. The October 2016 Warrants have a five-year term.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 11,719 and 200,391 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In July 2016, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 106,250 shares, from 94,141 to 200,391 shares, upon a favorable vote by the Company's stockholders. The Plans are administered by the Compensation and Stock Option Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the type, terms, conditions, option price and the duration of each award. As of June 30, 2017 there were 122,596 shares available to grant under the 2009 Stock Incentive Plan.

A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. Options and Restricted Stock granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee. Options granted under the Plans expire over varying terms, but not more than ten years from the date of grant.

For the three and six months ended June 30, 2017, the Company recognized compensation expense of approximately $24,000 and $46,000, respectively, relating to stock options granted to employees. For the same periods in 2016, the Company recognized compensation expense of approximately $19,000 and $0.1 million, respectively. There were 15,000 stock options awards granted during the six months ended June 30, 2017. There were no stock option awards

granted during the same period in 2016.

For the three and six months ended June 30, 2017, the Company recognized compensation expense of approximately $36,000 and $0.1 million, respectively, relating to restricted stock granted to employees. For the same periods in 2016, the Company recognized compensation expense of approximately $52,000 and $0.2 million, respectively. There were 92,250 shares of restricted stock granted during the six months ended June 30, 2017. There were approximately 4,688 shares of restricted stock awards granted for the same period in 2016.

(9) Fair Value Measurements
Derivative Warrant Liability

As disclosed in Note 8 of the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, the Company allocated part of the proceeds of public offerings in 2013, 2015 and 2016 of the Company's common stock to warrants issued in connection with those transactions. In addition, the Company recognized a discount to debt related to the initial fair value of warrants issued in connection with the June 2016 Convertible Notes discussed in further detail in Note 7 of the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. The valuation of the October 2013, February 2015, July 2015 Series A, June 2016 Series C and October 2016 warrants (collectively, the "Warrants") were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the Warrants as a current liability due to certain provisions relating to price adjustments and potential cash payments, as well as the holders' ability to exercise the warrants within twelve months of the reporting date and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period. Additionally, the Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing models against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the risk-free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The risk-free rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

For the three and six months ended June 30, 2017, the Company recorded pre-tax derivative warrant expense of approximately $38,000 and pre-tax derivative warrant income of $1.2 million, respectively. The resulting derivative warrant liabilities totaled approximately $43,000 at June 30, 2017. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at June 30, 2017 was determined by using option pricing models with the following assumptions:

	October 2016 Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	108.81%	104.84%	110.37%	201.39%
Risk-free interest rates	1.81%	1.55%	1.47%	1.27%
Expected life (in years)	4.27	3.06	2.63	1.33

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of June 30, 2017, 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	Balance at June 30, 2017
Liabilities				
Derivative instrument liabilities	$ —	$ —	$ 43	$ 43

For the periods ended June 30, 2017 and 2016, there were no transfers in or out of Level 1, 2 or 3 inputs.

The table below presents the activity within Level 3 of the fair value hierarchy for the six months ended June 30, 2017:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2016	$18,751
Total change in the liability included in earnings	(1,200)
Extinguishment of convertible note warrant	(17,489)
Fair value of warrants issued	—
Fair value of warrants exercised	(19)
Balance at June 30, 2017	$43

(10) 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. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

The following potentially dilutive securities were excluded from the computation of earnings per share as of June 30, 2017 and 2016 because their effects would be anti-dilutive:

	June 30, 2017	2016
Stock options	55,846	42,024
Unvested restricted shares	101,294	19,000
Warrants	36,848	7,427,491
Total	193,988	7,488,515

(11) 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 Company was notified by the Internal Revenue Service that they will be examining the tax return for calendar year 2013. The effect of the outcome cannot be reasonably estimated as the exam is presently ongoing. However, the Company does not expect any material change to its financial statements as a result of this audit. Any proposed adjustments would result in an adjustment to the net operating loss carryforward for which a valuation allowance has been provided against the full amount. The Company has not been audited by the international tax authorities or any states in connection with income taxes. The Company's New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company's tax years generally remain open to examination for all federal, state and foreign tax matters until its net operating loss carryforwards are utilized and the applicable statutes of limitation have expired. 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.

(12) Subsequent Events

On June 29, 2017, our Board authorized the establishment of two series of preferred stock designated as Series A Preferred Stock, $0.01 par value, and Series B Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for each such series of Preferred Stock which were filed with the State of Delaware on June 30, 2017 and July 5, 2017, respectively.

On July 2, 2017, we entered into an exchange agreement (the "Exchange") with one of our investors which had purchased certain senior secured convertible notes (the "Notes"), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the "Series A Preferred Stock"). The Exchange is being made in reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Stock shall be entitled to the whole number of votes equal to $4.2 million divided by $3.68 (the closing bid price on June 13, 2016, the date of issuance of the Notes as adjusted for the reverse stock split effected in July 2016) or 1,141,304 votes. The Series A Preferred Stock have no dividend, liquidation or other preferential rights to our common stock, and each share of Series A Preferred Stock shall be redeemable for the amount of $0.001, payable in cash, per share at our written election.

On July 11, 2017, we entered into an Amended and Restated Securities Purchase Agreement (the "Amended Purchase Agreement") with the investors which had purchased the Notes for the sale by the Company of 2,360 shares of Series B Preferred Stock (the "Series B Preferred Stock") at a purchase price of $1,000 per share, in a private placement. The aggregate gross proceeds for the sale of the Series B Preferred Stock is $2.0 million. The Company intends to use the proceeds from the transaction for general corporate purposes. The restricted shares of Series B Preferred Stock have no registration rights and thus will not be eligible for legend removal for a period of at least six months from the date of closing. This Amended Purchase Agreement amends the July 5, 2017 Securities Purchase Agreement (the "Purchase Agreement") into which we entered with certain institutional investors (the "Investors") for the sale by the Company of 2,360 shares of Series B Preferred Stock in a registered direct offering. The Series B Preferred Stock shall be entitled to the whole number of votes equal to $2.0 million divided by $0.1867 (the closing bid price on July 5, 2017, the date of sale of the Series B Preferred Stock), or 10,712,372 votes. The Series B Preferred Stock has no dividend, liquidation or other rights which are preferential to our common stock.

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, 2016 included in the Company's 2016 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, 2017 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, 2017 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 June 30, 2017 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, 2016 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 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 2016 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 in commercial development 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 for CHEMOSAT/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 overall survival in mOM, and a registration trial for intrahepatic cholangiocarcinoma (ICC) we plan to initiate in 2017. Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

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, development, early European commercial and United States regulatory activity 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 adequate reimbursement 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.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT/Melphalan/HDS represents a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver. We believe that CHEMOSAT/Melphalan/HDS is 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 2017 report, cancer is the second leading cause of death in the United States, with an estimated 600,920 deaths and 1,688,780 new cases expected to be diagnosed in 2017. 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 conducted 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. According to our 2016 research, 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.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers – including HCC and ICC – are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 40,710 new cases of HCC and ICC will be diagnosed in the United States in 2017. Approximately 75-90% of these patients are diagnosed with HCC. Excluding patients who are eligible for surgical resection or certain focal treatments, we estimate that approximately 15,000 patients with HCC in the United States and Europe may be eligible for treatment with Melphalan/HDS. We estimate that an additional 9,300 patients diagnosed with ICC may also be eligible for treatment with Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients 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%. Globally, with 782,000 new cases in 2012, HCC was the fifth most common cancer in men and the ninth in women according to GLOBOCAN. GLOBOCAN estimates indicate that HCC was responsible for 746,000 deaths in 2012 (9.1% of the total cancer deaths), making it the second most common cause of death from cancer worldwide.

The prognosis for primary liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society's Cancer Facts & Figures 2017 outlines the treatment options for HCC as follows: "Early stage liver cancer can sometimes be successfully treated with surgery to remove part of the liver (partial hepatectomy); however, few patients have sufficient healthy liver tissue for this option. Liver transplantation may be possible in individuals with small tumors who are not candidates for partial hepatectomy. Other treatment options include tumor ablation (destruction) or embolization (blocking blood flow). Few options exist for patients diagnosed at an advanced stage. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery and do not have severe cirrhosis."

Based on third party research, we estimate that up to 15,000 of the 65,000 patients diagnosed annually in the United States and Europe could be eligible candidates for treatment with the Melphalan/HDS. The FDA has granted orphan drug status to the Melphalan/HDS for treatment of patients with unresectable HCC. We believe that there is a large unmet medical need in first line therapy for patients with HCC, with Sorafenib the only currently approved systemic therapy in the United States, Europe and certain Asian markets.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the United States and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care. Based on third party research, 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.

About CHEMOSAT/Melphalan/HDS

CHEMOSAT/Melphalan/HDS administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with 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/Melphalan/HDS is repeatable, and a new disposable CHEMOSAT/Melphalan/HDS is used for each treatment. Patients treated in clinical are permitted up to six treatments. In non-clinical commercial settings patients have received up to 8 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/Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/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/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/Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2016, 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.

Prior Clinical Development

Our Phase 3 clinical trial and multi-arm Phase 2 clinical trial of the Melphalan/HDS with melphalan in patients with liver cancers are summarized below. The Phase 3 and Phase 2 clinical trials were subject to the terms and conditions of the Cooperative Research and Development Agreement (CRADA), between the Company and the National Cancer Institute (NCI). The Phase 3 trial was conducted under an FDA Special Protocol Assessment (SPA) and was conducted at centers throughout the United States.

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, a prestigious medical journal 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. We believe these results constitute a promising signal that warrants further clinical investigation.

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 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. 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/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/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.

FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the FOCUS Trial) - NCT02678572

In January 2016, we initiated a new pivotal Phase 3 clinical trial in hepatic dominant ocular melanoma with the first patient enrolled in February 2016 looking at overall survival of patients (length of time from treatment to death). Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety, efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial's treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

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 2016 we announced the addition of several prestigious cancer centers in the United States and Europe. We intend to include approximately 30-40 leading cancer centers in the United States and Europe in the FOCUS Trial.

The FOCUS Trial is being conducted under a SPA we concluded with the FDA in January 2016. Under the terms of the SPA, the FOCUS Trial is the only Phase 3 trial required for submission of an NDA.

There currently is no SOC for the treatment of hepatic dominant ocular melanoma. The Melphalan/HDS 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 approval of the Melphalan/HDS in the United States.

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

In March 2017 we announced another SPA agreement with the FDA for the design 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 (Pivotal ICC Trial). Under the SPA, the Pivotal ICC 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. We expect to begin patient enrollment in the study in the Fall of 2017. This Pivotal ICC Trial is designed to be cost effective and pursued in a financially prudent manner. Given the sequential nature of the trial design, our investment in this study will be modest in 2017 as the Melphalan/HDS segment of the study will not occur until late in the year. The SPA agreement for this trial indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS in ICC.

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 is intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. The trial will evaluate overall response rate via modified Response Evaluation Criteria in Solid Tumors (mRECIST), progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life

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. Hospitals in Germany and Italy are participating in this trial.

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 collection for the ICC cohort is ongoing. We will announce results for this cohort once the data are fully mature.

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 are being submitted for publication by the European investigators, and details of these findings will be announced when publically available.

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 will close the Phase 2 trials in order to focus available resources on the FOCUS Trial and the ICC Pivotal 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 this 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 (IITs) in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in the Netherlands. We are planning two additional IITs – one for colorectal carcinoma metastatic to the liver at Heidelberg University in Heidelberg, Germany and one for pancreatic carcinoma metastatic to the liver at Spire Hospital in Southampton, England. 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 data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe. Cancer centers in Germany, the United Kingdom, and the Netherlands are participating in the registry and patient enrollment has begun.

Recent Data Presentations

In July 2017, the Journal of Cancer Research and Clinical Oncology published an analysis of clinical findings from 29 Hannover Medical School patients who were treated with percutaneous hepatic perfusion (PHP®) therapy with Melphalan/HDS as last-line therapy for primary and secondary liver tumors. Hannover Medical School physicians treated 29 patients with a total of 54 PHP procedures. Patients received as many as five treatments each, with an average of two per patient. Nineteen patients were diagnosed with unresectable liver metastases that arose from solid tumors, including 11 cases of ocular melanoma, and the remaining 10 patients had hepatocellular or cholangiocarcinoma.

Across all patients, the overall response rate (ORR) was 19.2 percent, with ocular melanoma patients experiencing the highest ORR (33.3 percent). As has been published previously, high tumor volumes negatively impact overall survival (OS). Median OS was 261 days for the entire patient group. Two patients with cholangiocarcinoma and one patient with ocular melanoma had the longest survival with 566, 465, and 477 days respectively. Overall, PHP with Melphalan/HDS was well tolerated. Complications including thrombocytopenia, cardiovascular events, ulcerous bleeding, and edema were reported. These results are summarized in the Journal of Cancer Research and Clinical Oncology article, “Safety and Efficacy of Chemosaturation in Patients with Primary and Secondary Liver Tumors.”

In February 2017, we announced that the American Journal of Clinical Oncology published a single-center retrospective review, in which authors found that investigational PHP with Melphalan/HDS offers promising results with a doubling of overall survival and significantly longer progression-free survival (PFS) and hPFS than other targeted therapies. The review, “Hepatic Progression-free and Overall Survival After Regional Therapy to the Liver for Metastatic Melanoma,” was written by a team from the Moffitt Cancer Center who analyzed clinical outcomes of three different non-randomized approaches used to treat 30 patients with liver metastases primarily resulting from ocular melanoma and skin melanoma. A third of the patients received PHP using melphalan delivered via the Delcath Hepatic Delivery System (Melphalan/HDS), 12 received chemoembolization (CE) and six received radioembolization with yttrium-90 (Y90). Two patients crossed over once their cancer progressed – one from PHP to Y90 and one from CE to PHP.

The paper’s authors concluded that patients who received PHP with Melphalan/HDS had significantly longer median hPFS at 361 days compared to 54 days for Y90 and 80 days for CE, as well as a longer median PFS at 245 days compared to 54 days for Y90 and 52 days for CE. Median overall survival was also longest for PHP at 608 days compared to 295 days for Y90 and 265 days for CE. The authors noted that further studies, including a randomized controlled trial, would be needed to confirm whether clinically superior outcomes can be achieved with PHP compared to other liver-targeted treatments.

Side effects following all treatments were similar, with most complications recorded as anorexia, abdominal pain, fatigue and nausea. Laboratory irregularities, such as thrombocytopenia and abnormal liver function tests, were seen immediately after treatment in some patients, but returned to baseline within a few days.

Also in February 2017, we announced results of a retrospective, multicenter study presented at the Regional Cancer Therapies 12th International Symposium in an oral presentation titled, "Percutaneous Hepatic Perfusion for Unresectable Metastatic Ocular Melanoma to the Liver: A Multi-Institutional Report of Outcomes." This analysis demonstrated that 45.7 percent of patients with ocular melanoma that metastasized to the liver who underwent PHP using Melphalan/HDS experienced a complete or partial response. The study further showed that among those who responded to treatment, overall survival was projected to be more than three years. The analysis was conducted by teams from Moffitt Cancer Center in Tampa, Fla., and the University of Southampton in the United Kingdom. The presentation was led by Dr. Alexandra Gangi of the Moffitt Cancer Center.

The analysis reviewed outcomes of 49 patients treated between 2008 and 2016 with Melphalan/HDS at either the Moffitt Cancer Center or the University of Southampton. Patients underwent a total of 115 PHP treatments. The median number of treatments per patient was two, with patients receiving one-to-six treatments.

Hepatic response to PHP was evaluable in 46 patients, among whom 45.7 percent showed complete or partial response, and 37.0 percent had stable disease. Median overall survival was not reached, but was projected to be 657 days (1.8 years). Among patients with a complete or partial response, overall survival was projected to be 1,207 days. Most common side effects following treatment were anemia, thrombocytopenia and neutropenia.

Market Access & Commercial Clinical Adoption

European Union

Our immediate market access and clinical adoptions efforts continue to be 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 EU 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, 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. Earlier this year we were delighted to report that SPIRE Southampton Hospital in the U.K. surpassed 100 treatments with CHEMOSAT since initiating procedures in December 2013, a milestone also recently achieved by one of our sites in Germany. We also continue to see the average number of repeat treatments performed on a per patient basis consistently increase, also earlier this year, we reported our first patient to receive eight CHEMOSAT treatments.

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, the Company is 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. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are renegotiated annually.

United Kingdom

In the United Kingdom, though Delcath and our participating cancer centers identified existing Healthcare Resource Groups (HRG) code(s), we have been advised that hospitals have not used it for coverage of CHEMOSAT related costs. We continue to work with the HRG organization that decides on new HRG codes toward receipt of a dedicated and permanent reimbursement code in the future.

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 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. NICE stated that this research may take the form of observational studies. With continued enrollment in our Phase 2 HCC and ICC trial in 2016, we believe the data generated from these studies will help provide supporting clinical data and address the concerns raised by NICE relative to survival, quality of life and adverse events. NICE may decide to conduct a Technology Appraisal of CHEMOSAT thereafter, the outcome of which could influence the long-term reimbursement status.

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.

Spain

In April 2016, we announced that the General and Digestive Surgery team at HM Sanchinarro University Hospital had activated the hospital's CHEMOSAT program. The Sanchinarro team successfully performed three procedures with CHEMOSAT, using the procedure to treat patients with peripheral cholangiocarcinoma and neuroendocrine tumors liver metastases. HM Sanchinarro University Hospital is the second center in Spain to offer CHEMOSAT treatments.

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. We believe that Hacettepe University can serve as an important hub 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. In Spain, the Company has determined that there was no benefit to continuing with an indirect model and therefore terminated its relationship with its distributor in Spain and is now represented in Spain through a sales agency. 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.

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 eight U.S. utility patents, one U.S. design patent, six pending U.S. utility patent applications (one of which has been allowed), four issued foreign counterpart utility patents (including the validation of one European patent in two European countries, and the validation of another European patent in four European countries), six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications (one of which has been allowed).

In July 2017, one of our pending patent applications for our chemotherapy filtration system was approved by the U.S. Patent Office. When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT/Melphalan/HDS that will enable us to expand our platform 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.

Certain of our United States and foreign patents have already expired and other patents relating to the CHEMOSAT/Melphalan/HDS will expire in the future. 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.

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 reviewed the medical devices legislative framework in 2012 with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. We do not believe the adopted regulatory changes will impact our business at this time, though future changes to 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.

Recent Financial Transactions

In July, we issued two series of preferred stock (Series A Preferred Stock and Series B Preferred Stock) in transactions with holders of our 2016 convertible notes. The Series A shares were issued to address a short-term valuation issue for common shares delivered to the note holders to close an installment period. Through the Series A Preferred Shares placement, we were able to value the open installment shares such that the amount of debt remaining under the Convertible Note was reduced by $4.2 million. The Series B Preferred Shares, which are convertible to common shares at $0.153, allowed us to raise $2.0 million in unrestricted cash. This was critical to our ongoing operations because we are unable to access cash in the restricted accounts related to the Convertible Note.

Proposal on Effecting a Reverse Stock Split

On July 26, 2017 the Company filed a Schedule 14A detailing a proposed reverse stock split, subject to shareholder approval. To continue to fund our operations and support our clinical programs, we need the ability to issue common shares, both to service the amortization of our Convertible Note and to explore alternative equity financing. However, we are currently at the threshold of the Authorized Shares limit in our Certificate of Incorporation. Without a sufficient number of authorized shares, we are unable to access the $11.8 million of cash in the restricted account associated with the Convertible Notes issued last year, or to undertake any type of equity fund raise. The proposed reverse split of our common shares will reduce the shares outstanding and provide us with the flexibility to raise equity capital and support our important clinical trials and our commercial efforts in Europe.

Effecting the reverse stock split will also allow Delcath to remain in compliance with NASDAQ exchange stock listing requirements, which provides liquidity and other important benefits to the Company and its investors. It is

important to note that the floor price for the Convertible Note will adjust with the effected reverse stock split ratio to a minimum of $1.00. We believe this should serve to support the stock price following a split and reduce future potential dilution related to the Convertible Note.

For these reasons, the Company's Board of Directors encourage investors to support the proposed reverse stock split in order for Delcath to move forward successfully. All investors are encouraged to read our Definitive Schedule 14A in detail for full information regarding the proposed reverse stock split.

Results of Operations for the three and six months ended June 30, 2017; Comparisons of Results of Operations for the three and six months ended June 30, 2016

Three months ended June 30, 2017 and June 30, 2016

Revenue

The Company recorded approximately $0.6 million in revenue related to product sales for the three months ended June 30, 2017 and $0.5 million in revenue related to product sales for the three months ended June 30, 2016. 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 June 30, 2017, the Company recorded cost of goods sold of approximately $0.1 million compared to $0.2 million for the three months ended June 30, 2016, primarily related to rounding differences.

Selling, General and Administrative Expenses

For the three month periods ended June 30, 2017 selling, general and administrative expenses were $2.5 million compared to $2.3 million for the three months ended June 30, 2016. The increase is due to an increase in personnel related expenses and costs associated with the timing of Company’s annual meeting being held in the second quarter this year versus the third quarter in the prior year.

Research and Development Expenses

For the three month periods ended June 30, 2017 and 2016, research and development expenses increased to $2.5 million from $1.9 million, primarily due to the ongoing enrollment of our Phase 3 trial which is discussed in further detail in the Current Clinical Development Program section above.

Other Income/Expense and Interest Expense

Other income (expense) increase is related to the gain on the extinguishment of the June 2016 Series C Warrants discussed in Note 7 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q .

Interest expense is related to:

1. the restructuring lease liability discussed in Note 6 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 7 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.

Derivative Instrument Expense

For the three months ended June 30, 2017 derivative instrument expense decreased to approximately $38,000 from $1.2 million for the three months ended June 30, 2016. The decrease of $1.1 million is due to the extinguishment of the Series C Warrants and the mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 7 and Note 9 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 June 30, 2017, of $2.0 million, a decrease of $4.7 million, or 70.9%, compared to a net loss of $6.7 million for the same period in 2016. This decrease in net loss is primarily due to a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants which was offset by a $5.3 million increase in interest expense related to the convertible note, both non-cash items and discussed further in Note 7 of the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. Additionally, there was a $1.2 million decrease in the change in the fair value of the warrant liability, a non-cash item, offset by a $0.8 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Six months ended June 30, 2017 and June 30, 2016

Revenue

The Company recorded approximately $1.3 million in revenue related to product sales for the six months ended June 30, 2017 and $0.9 million in revenue related to product sales for the six months ended June 30, 2016. 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 six months ended June 30, 2017, the Company recorded cost of goods sold of approximately $0.4 million compared to $0.3 million for the six months ended June 30, 2016. The increase in cost of goods sold is commensurate with the increase in sales.

Selling, General and Administrative Expenses

For the six months ended June 30, 2017 the Company recorded selling, general and administrative expenses of approximately $4.9 million compared to $4.7 million for the same period in 2016. The increase is due to an increase in personnel and costs associated with the timing of Company’s annual meeting being held in the second quarter this year versus the third quarter in the prior year.

Research and Development Expenses

For the six months ended June 30, 2017 and 2016, research and development expenses increased to $4.8 million from $3.3 million, primarily due to the ongoing enrollment of our Phase 3 trial during 2016 which is discussed in further detail in the Current Clinical Development Program section above.

Other Income/Expense and Interest Expense

Other income (expense) increase is related to the gain on the extinguishment of the June 2016 Series C Warrants discussed in Note 7 of the Company’s interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q .

Interest expense is related to:

1. the restructuring lease liability discussed in Note 6 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 7 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.

Derivative Instrument Income

For the six months ended June 30, 2017 derivative instrument income increased to $1.2 million from $0.5 million for the six months ended June 30, 2016. The increase of $0.7 million is due to the extinguishment of the Series C Warrants and the mark-to-market adjustments to the Warrant liability as discussed in more detail in Note 7 and Note 9

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 six months ended June 30, 2017, of $13.3 million, an increase of $4.8 million, or 56.5%, compared to a net loss of $8.5 million for the same period in 2016. This increase in net loss is primarily due to a $13.7 million increase in interest expense primarily related to the amortization of debt discounts, offset by a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants, both non-cash items, discussed further in Note 7 of the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. Additionally, there was a $1.8 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives, offset by $0.4 million increase in gross profit and a $0.7 million increase in the change in the fair value of the warrant liability, a non-cash item.

Liquidity and Capital Resources

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 June 30, 2017, the Company had cash and cash equivalents totaling $1.8 million, as compared to cash and cash equivalents totaling $4.4 million and $7.5 million at December 31, 2016 and June 30, 2016, respectively. In addition, the Company has $12.9 million in restricted cash primarily related to the Convertible Notes discussed further in Note 7 of the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. During the six months ended June 30, 2017 the Company used $8.1 million of cash in its operating activities, which compares to $7.0 million used for operating activities during the comparable period in 2016. Assuming the Company is able to effect a reverse stock split as proposed in its recent consent solicitation statement filed with the SEC on July 26, 2017, management believes that its capital resources are adequate to fund operating activities through the end of 2017.

Our consolidated financial statements as of June 30, 2017 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, and 2016 including registered direct offerings in 2007, 2009 and 2013, "at the market" equity offering programs in 2012 and 2013, and by a private placement of convertible notes in 2016 and preferred stock in 2017. For a detailed discussion of the Company's various sales of securities see Note 8 to the Company's financial statements contained in this Quarterly Report on Form 10-Q.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $76.0 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. Pursuant to SEC regulations, so long as the Company's public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

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 2016 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 October 2013, the Company completed the sale of 81,875 shares of its common stock and the issuance of warrants to purchase approximately 37,000 common shares (the "2013 Warrants") pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 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. At June 30, 2017, the 2013 Warrants were exercisable at $112.64 per share with approximately 37,000 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 153,750 shares of its common stock and the issuance of warrants to purchase 69,000 common shares (the "February 2015 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 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 June 30, 2017, the February 2015 Warrants were exercisable at $0.14 per share with approximately 30,000 warrants outstanding. The February 2015 Warrants have a five-year term.

In July 2015, the Company completed the sale of 0.6 million Units consisting of 0.6 million shares of its common stock, Series A Warrants to purchase up to 0.4 million common shares ("Series A Warrants") and Series B Warrants to purchase Units consisting of up to 0.6 million common shares ("Series B Warrants") and 0.4 million Series A Warrants per unit pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the 2015 Series A Warrants and Series B Warrants. The exercise price of both series of warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is 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. During the three months ended March 31, 2016, approximately 0.1 million Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 0.4 million Series B Warrants expired on January 29, 2016 and the remaining liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 0.1 million Series A Warrants were issued. At June 30, 2017, the Series A Warrants were exercisable at $0.14 with approximately 0.2 million warrants outstanding. The Series A Warrants have a five-year term. There were approximately 0.1 million July 2015 Series A Warrants exercised during the six months ended June 30, 2017 for proceeds of approximately $15,000.

In June 2016, the Company entered into a Securities Purchase Agreement pursuant to which the Company issued $35.0 million in principal face amount of senior secured convertible notes of the Company (the "Notes") and related Series C Warrants (the "Series C Warrants") to purchase 6.8 million additional shares of the Company's common stock. The Company allocated an estimated fair value of $27.8 million to the Series C Warrants. On April 2, 2017 the

Company entered into warrant repurchase agreements with each of the investors named on the Schedule of Buyers attached to the SPA. Pursuant to the Warrant Repurchase Agreements, each investor agreed to a Controlled Account Release, in an aggregate amount equal to $7.9 million, which funds in each case are to be paid to the respective investor, in exchange for cancellation of the Series C Warrants issued to each investor under the SPA.

In October 2016, the Company completed the sale of 425,000 shares of its common stock and the issuance of warrants to purchase 148,750 common shares (the "October 2016 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 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 June 30, 2017, the October 2016 Warrants were exercisable at $0.14 per share with 0.1 million warrants outstanding. The October 2016 Warrants have a five-year term.

The proceeds allocated to the 2013 Warrants, February 2015 Warrants, the July 2015 Series A Warrants, and the October 2016 Warrants (the "Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As a result, for the six months ended June 30, 2017, the Company recorded pre-tax derivative instrument income of $1.2 million. The fair value of the Warrants totaled $0.04 million at June 30, 2017. Management expects that the warrants outstanding at June 30, 2017 will either be exercised or expire worthless. The fair value of the Warrants at June 30, 2017 was determined by using option pricing models assuming the following:

	October 2016 Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	108.81%	104.84%	110.37%	201.39%
Risk-free interest rates	1.81%	1.55%	1.47%	1.27%
Expected life (in years)	4.27	3.06	2.63	1.33

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 June 30, 2017 (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 June 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings
Not Applicable.

Item 1A. Risk Factors
Delcath's 2016 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. There have been no material changes in these risk factors since such disclosure.

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

On July 11, 2017, we entered into an Amended and Restated Securities Purchase Agreement (the "Amended Purchase Agreement") with certain institutional investors for the sale by the Company of 2,360 shares of Series B Preferred Stock (the "Series B Preferred Stock") at a purchase price of $1,000 per share, in a private placement. The aggregate gross proceeds for the sale of the Series B Preferred Stock is $2.0 million. The Company intends to use the proceeds from the transaction for general corporate purposes. The restricted shares of Series B Preferred Stock have no registration rights and thus will not be eligible for legend removal for a period of at least six months from the date of closing. This Amended Purchase Agreement amends the July 5, 2017 Securities Purchase Agreement (the "Purchase Agreement") into which we entered with certain institutional investors (the "Investors") for the sale by the Company of 2,360 shares of Series B Preferred Stock in a registered direct offering. The Series B Preferred Stock shall be entitled to the whole number of votes equal to $2.0 million divided by $0.1867 (the closing bid price on July 5, 2017, the date of sale of the Series B Preferred Stock), or 10,712,372 votes. The Series B Preferred Stock has no dividend, liquidation or other rights which are preferential to our common stock.

Item 3. Defaults upon Senior Securities
Not Applicable.

Item 4. Mine Safety Disclosures
Not Applicable.

Item 5. Other Information
Not Applicable.

Item 6. Exhibits

Exhibit No.		Description
10.1	(1)	Securities Purchase Agreement, dated as of June 6, 2016
10.2	(2)	Form of Senior Secured Convertible Note
10.3	(3)	Form of Warrant
10.4	(4)	Form of Security and Pledge Agreement
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.

(1) Filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 7, 2016 and incorporated by reference

(2) Filed as Exhibit A to the Securities Purchase Agreement filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 7, 2016 and incorporated by reference

(3) Filed as Exhibit B to the Securities Purchase Agreement filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 7, 2016 and incorporated by reference

(4) Filed as Exhibit C to the Securities Purchase Agreement filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 7, 2016 and incorporated by reference

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DELCATH SYSTEMS, INC.

SIGNATURES

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

August 8, 2017 DELCATH SYSTEMS, INC.
(Registrant)

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

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

DELCATH SYSTEMS, INC.

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