DELCATH SYSTEMS, INC.
Form 10-Q
November 05, 2014

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

FORM 10-Q

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

For the quarterly period ended September 30, 2014
or

o 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.)

1301 Avenue of the Americas, 43FL
(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 x No o

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 x No o

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

Large accelerated filer	o		Accelerated filer	o
Non-accelerated filer	x	(Do not check if a smaller reporting company)	Smaller reporting company	o

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

As of November 4, 2014, 9,708,832 shares of the Company's common stock, $0.01 par value, were outstanding.

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

	September 30, 2014	December 31, 2013
ASSETS		
Current assets		
Cash and cash equivalents	$23,323	$31,249
Accounts receivables, net	157	349
Inventories, net	518	719
Prepaid expenses and other current assets	752	1,711
Total current assets	24,750	34,028
Property, plant and equipment, net	2,118	3,069
Total assets	$26,868	$37,097
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$114	$582
Accrued expenses	4,426	3,740
Warrant liability	555	2,310
Total current liabilities	5,095	6,632
Other non-current liabilities	1,088	366
Total liabilities	6,183	6,998
Commitments and contingencies (Note 11)	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2014 and December 31, 2013	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 9,515,175 and 8,394,397 shares issued and 9,448,903 and 8,392,641 shares outstanding at September 30, 2014 and December 31, 2013, respectively *	95	84
Additional paid-in capital	264,140	259,102
Accumulated deficit	(243,568)	(229,132)
Treasury stock, at cost; 1,757 shares at September 30, 2014 and December 31, 2013 *	(51)	(51)
Accumulated other comprehensive income	69	96
Total stockholders' equity	20,685	30,099
Total liabilities and stockholders' equity	$26,868	$37,097

* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
REVENUES				
Product revenues	$217	$72	$778	$152
Other revenues	—	—	—	300
Total revenues	217	72	778	452
COSTS OF SALES				
Costs of goods sold	(50)	(23)	(209)	(386)
Gross profit	167	49	569	66
OPERATING EXPENSES				
Selling, general and administrative	4,538	4,573	12,956	16,919
Research and development	683	2,178	3,632	10,639
Total operating expenses	5,221	6,751	16,588	27,558
Loss from operations	(5,054)	(6,702)	(16,019)	(27,492)
OTHER INCOME (EXPENSE)				
Change in fair value of warrant liability, net	519	(497)	1,612	2,345
Interest income	2	2	4	18
Other income (expense)	(25)	(9)	(33)	(404)
Net loss	$(4,558)	$(7,206)	$(14,436)	$(25,533)
LOSS PER COMMON SHARE				
Basic and diluted loss per common share *	$(0.48)	$(1.15)	$(1.54)	$(4.35)
WEIGHTED AVERAGE COMMON SHARES				
Basic and diluted weighted average common shares outstanding *	9,447,887	6,254,312	9,391,793	5,875,490
OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	$(6)	$15	$(27)	$384
Comprehensive loss	$(4,564)	$(7,191)	$(14,463)	$(25,149)

* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Nine months ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(14,436)	$(25,533)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	321	407
Restricted stock compensation expense	96	179
Depreciation expense	742	866
Provision for inventory obsolescence	118	17
Warrant liability fair value adjustment	(1,612)	(2,345)
Loss on write-downs and disposals of equipment	147	5
Non-cash interest income	—	(1)
Changes in assets and liabilities:		
Decrease in prepaid expenses and other current assets	937	305
Decrease in accounts receivable	187	36
Decrease in inventories	73	133
Increase (decrease) in accounts payable and accrued expenses	275	(3,149)
Increase in other non-current liabilities	723	189
Net cash used in operating activities	(12,429)	(28,891)
Cash flows from investing activities:		
Purchase of property, plant and equipment	—	(113)
Proceeds from sales of property, plant and equipment	37	—
Net cash provided by (used in) investing activities	37	(113)
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of warrants	4,489	32,218
Net cash provided by financing activities	4,489	32,218
Foreign currency effects on cash	(23)	795
Net (decrease) increase in cash and cash equivalents	(7,926)	4,009
Cash and cash equivalents:		
Beginning of period	31,249	23,726
End of period	$23,323	$27,735
Supplemental non-cash activities:		
Fair value of warrants exercised	$143	$219

See accompanying Notes to Condensed Consolidated Financial Statements

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Notes to the Condensed Consolidated Financial Statements

(1) General

The interim Condensed Consolidated Financial Statements of Delcath Systems, Inc. ("Delcath" or the "Company") for the three and nine months ended September 30, 2014 and 2013 should be read in conjunction with the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K ("Annual Report") for the year ended December 31, 2013, which has been filed with the Securities Exchange Commission ("SEC") 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.

On April 8, 2014, the Company effected a one-for-sixteen (1:16) reverse stock split. Refer to Note 7 Stockholders' Equity of these Condensed Consolidated Financial Statements for further information.

Description of Business

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary 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 the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic liver cancers.

In the United States (U.S.), Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for Generation Two CHEMOSAT. The right to affix the CE Mark allows the Company to market and sell CHEMOSAT in Europe. The Company has initiated plans to investigate Melphalan/HDS for primary liver cancer.

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations through the next twelve months, but anticipates that additional working capital will be required to continue operations. 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.

Basis of Presentation

These interim Condensed Consolidated Financial Statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the SEC's instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all entities controlled by Delcath and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim Condensed Consolidated Financial Statements, in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's

results of operations, financial position and cash flows for the interim periods ended September 30, 2014 and 2013; 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.

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, 2013.

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Recently Adopted Accounting Pronouncements

In March 2013, the FASB issued ASU 2013-05, Foreign Currency Matters (Topic 830): Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity, which permits an entity to release cumulative translation adjustments into net income when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. Accordingly, the cumulative translation adjustment should be released into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided, or, if a controlling financial interest is no longer held. The revised standard became effective for fiscal years beginning after December 15, 2013. The Company adopted this guidance effective January 1, 2014. The Company’s adoption of this standard did not have a material impact on its consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

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 annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company expects to adopt this guidance when effective, and the potential impact on our financial statements is not currently estimable.

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (“ASU 2014-12”). ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015, with early adoption permitted. The Company expects to adopt this guidance when effective, and does not anticipate that this guidance will materially impact its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements — Going Concern, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). ASU 2014-15 requires management to assess an entity’s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (1) provides a definition of the term substantial doubt, (2) requires an evaluation every reporting period including interim periods, (3) provides principles for considering the mitigating effect of management’s plans, (4) requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans, (5) requires an express statement and other disclosures when substantial doubt is not alleviated, and (6) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company expects to adopt this guidance when effective, and at the current time does not believe that it has met conditions which would subject its consolidated financial statements to the additional disclosures required by this guidance.

(2) Inventories

Inventories consist of the following:

(in thousands)	September 30, 2014	December 31, 2013
Raw materials	$ 172	$ 249
Work-in-process	252	364
Finished goods	94	106
Total inventory	$ 518	$ 719

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(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	September 30, 2014	December 31, 2013
Kits for clinical use	$ 227	$ 287
Insurance premiums	184	407
Professional fees	160	377
Other[1]	181	640
Total prepaid expenses and other current assets	$ 752	$ 1,711

[1] Other consists of various prepaid expenses and other current assets with no individual item accounting for more than 5% of the total balance at September 30, 2014 and December 31, 2013.

(4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	September 30, 2014	December 31, 2013
Enterprise hardware and software	$ 1,982	$ 2,143
Leaseholds	1,642	1,749
Equipment	1,350	1,552
Furniture	955	957
Buildings and land	603	603
Property, plant and equipment, gross	6,532	7,004
Accumulated depreciation	(4,414)	(3,935)
Property, plant and equipment, net	$ 2,118	$ 3,069

Depreciation expense for the three and nine months ended September 30, 2014 was approximately $0.2 million and $0.7 million, respectively, as compared to approximately $0.3 million and $0.9 million for the same periods in 2013.

(5) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	September 30, 2014	December 31, 2013
Compensation, excluding taxes	$ 2,781	$ 1,866
Deferred rent	71	485
Professional fees	282	360
Short-term portion of lease restructuring	334	–
Other[1]	958	1,029

Total accrued expenses	$ 4,426	$ 3,740

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at September 30, 2014 and December 31, 2013.

In November 2013, the Board of Directors approved an Employee Retention Program for certain key employees, including the Company's executive officers. The key employees will be eligible to receive a cash retention bonus payment equal to fifty percent (50%) of their current annual salary if they remain employed by the Company through March 31, 2015. The expense related to this program is being accrued ratably over the required service period and has been included in Accrued expenses on the Condensed Consolidated Balance Sheets and in both Selling, general and administrative and Research and development on the Condensed Consolidated Statements of Operations.

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For a description of the Company's lease restructuring liability refer to Note 6 Restructuring Expenses of these Condensed Consolidated Financial Statements.

(6) Restructuring Expenses

During 2013, the Company implemented workforce restructurings to reduce operating costs, better focus its organizational structure, increase efficiency and concentrate financial resources on its clinical development program and European commercialization activity. This resulted in a total reduction in the Company's workforce by 50 employees. During the second and third quarters of 2014, the Company implemented additional workforce restructurings that resulted in a total reduction in the Company's workforce by eight employees. As a result of termination benefits provided to these 58 employees the Company has incurred a total restructuring charge of approximately $5.3 million for employee related expenses. At September 30, 2014, the remaining restructuring reserve of approximately $1.4 million is included in Accrued expenses on the Condensed Consolidated Balance Sheets.

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, during the quarter ended June 30, 2014, the Company implemented a plan to vacate and sub-lease 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"), and had vacated and relinquished the premises to the sub-tenant as of June 30, 2014. Pursuant to Sub-lease #1, the sub-lease term commenced on July 1, 2014 and will expire on March 30, 2021, concurrent with the expiration of the Lease Agreement between Delcath and the landlord dated February 5, 2010 and subsequently modified by a Lease Modification, Extension and Additional Space Agreement between Delcath and the landlord dated September 27, 2010 (together the "Prime Lease"). At June 30, 2014, the Company's future rent obligations for Suite 3500 under the Prime Lease over the remaining lease term of 81 months totaled approximately $3.6 million. Under Sub-lease #1 the Company will receive future sub-lease rental receipts totaling approximately $2.6 million, resulting in net future cash outflows of approximately $1.0 million. In accordance with ASC 420, Exit or Disposal Cost Obligations, the Company calculated the fair value of the remaining net cash flow liability for Suite 3500 and recorded a lease restructuring reserve of approximately $0.9 million as of June 30, 2014. Additionally, during the quarter ended June 30, 2014, the Company recorded contract termination costs related to Sub-lease #1 of approximately $150,000 and wrote off approximately $50,000 of unamortized leasehold improvements related to Suite 3500. The expenses related to this lease restructuring were recorded in Selling, general and administrative on the Condensed Consolidated Statements of Operations.

On August 18, 2014, the Company entered into a sub-lease agreement ("Sub-lease #2") with a third party for the remaining one-half of office space at its 810 Seventh Avenue office ("Suite 3505"). On September 24, 2014, the Company received written consent from the landlord of the building with respect to Sub-lease #2, and had vacated and relinquished the premises to the sub-tenant as of September 30, 2014. Pursuant to Sub-lease #2, the sub-lease term commenced on October 1, 2014 and will expire concurrently with the expiration of the Prime Lease on March 30, 2021. At September 30, 2014, the Company's future rent obligations for Suite 3505 under the Prime Lease over the remaining lease term of 78 months totaled approximately $3.4 million. Under Sub-lease #2 the Company will receive future sub-lease rental receipts totaling approximately $2.6 million, resulting in net future cash outflows of approximately $0.8 million. In accordance with ASC 420, Exit or Disposal Cost Obligations, the Company calculated the fair value of the remaining net cash flow liability for Suite 3505 and recorded a lease restructuring reserve of approximately $0.7 million as of September 30, 2014. Additionally, during the quarter ended September 30, 2014, the Company recorded contract termination costs related to Sub-lease #2 of approximately $150,000. The expenses related to this lease restructuring were recorded in Selling, General and Administrative expenses on the Condensed Consolidated Statements of Operations. As of September 30, 2014, the total remaining lease restructuring liability for

its leased office space at 810 Seventh Ave was approximately $1.4 million, of which approximately $0.3 million and $1.1 million were included in Accrued expenses and Other non-current liabilities on the Condensed Consolidated Balance Sheets, respectively.

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The following table provides the year-to-date activity of the Company's restructuring reserves as of September 30, 2014:

(in thousands)	Employee Costs	Operating Lease
Reserve balance as of December 31, 2013	$ 2,019	$ –
Charges	1,327	1,547
Payments / utilizations	(1,990)	(125)
Reserve balance as of September 30, 2014	$ 1,356	$ 1,422

(7) Stockholders' Equity

Stock Issuances

Reverse Stock Split

On February 24, 2014, 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. The reverse stock split became effective on April 8, 2014 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 close of the NASDAQ market on April 8, 2014 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 number of common shares authorized or the par value per share of Delcath common stock, which remain 170,000,000 and $0.01, respectively. All current and prior period amounts related to shares, share prices and earnings per share, presented in these Condensed Consolidated Financial Statements and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

At-the-Market ("ATM") Programs

In December 2011, the Company entered into an agreement with Cowen and Company, LLC ("Cowen") to sell shares of its common stock, par value $.01 per share, from time to time, through an ATM equity offering program having aggregate sales proceeds of $39.8 million, under which Cowen would act as sales agent. During the first quarter of 2013, the Company sold approximately 14.2 million shares of its common stock under this ATM program for proceeds of approximately $20.9 million, with net cash proceeds after related expenses of approximately $20.8 million, and successfully completed the program. As of March 31, 2013, there were no shares of common stock of the Company remaining for sale under this ATM program.

In March 2013, the Company entered into a new agreement with Cowen to sell shares of the Company's common stock, par value $.01 per share, from time to time, through an ATM equity offering program having aggregate sales proceeds of $50.0 million, under which Cowen will act as sales agent. During the year ended December 31, 2013, the Company sold approximately 1.0 million shares of its common stock under this ATM program for proceeds of approximately $5.0 million, with net cash proceeds after related expenses of approximately $4.8 million. During the first quarter of 2014 the Company sold an additional 1.0 million shares of its common stock under this ATM program for proceeds of approximately $4.4 million, with net cash proceeds after related expenses of approximately $4.4 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-187230). The net

proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. There were no shares of common stock sold under the ATM program during the second or third quarters of 2014. As of September 30, 2014, the Company has approximately $40.4 million remaining under the program subject to market conditions and certain limitations.

Committed Equity Financing Facility (“CEFF”) Program

In December 2012, the Company entered into a two-year agreement with Terrapin Opportunity, L.P. (“Terrapin”) for a CEFF program. Under the agreement Terrapin committed to purchase up to $35.0 million of Delcath common stock over a 24-month term. Since inception, the Company has sold approximately 0.5 million shares of its common stock through the program for total proceeds of approximately $11.1 million, with net cash proceeds after related expenses of approximately $10.8 million. As a result, there was approximately $23.9 million available under this CEFF program as of September 30, 2014. The shares were issued pursuant to an effective registration statement on Form S-3 (333-183675). The net proceeds have been used for general corporate purposes including, but not limited to, commercialization of our products, funding of our clinical trials, obtaining regulatory approvals, capital expenditures and general working capital needs. The Company does not anticipate selling any additional shares before the agreement expires in December 2014.

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Warrants

In June 2009, the Company completed the sale of 0.1 million shares of its common stock and the issuance of warrants to purchase 0.1 million common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's October 2013 sale of common stock and warrants. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the six months ended June 30, 2014, 35,000 2009 Warrants were exercised for net proceeds of approximately $0.1 million. The 2009 Warrants had a five-year term which expired on June 15, 2014. The remaining liability after warrant exercises was credited to pre-tax derivative instrument income as of June 30, 2014.

In May 2012, the Company completed the sale of 1.0 million shares of its common stock and the issuance of warrants to purchase 0.3 million common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's October 2013 sale of common stock and warrants. At September 30, 2014, the 2012 Warrants were exercisable at $2.56 per share with approximately 260,000 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the nine months ended September 30, 2014, approximately 14,000 2012 Warrants were exercised for net proceeds of approximately $34,000.

In October 2013, the Company completed the sale of 1.3 million shares of its common stock and the issuance of warrants to purchase approximately 0.6 million 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 2013 Warrants became exercisable on April 30, 2014 and at September 30, 2014, the 2013 Warrants were exercisable at $7.04 per share with approximately 0.6 million warrants outstanding. The 2013 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. There were no 2013 Warrants exercised during the nine months ended September 30, 2014.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 187,500, and 406,250 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. 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.

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 granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the nine months ended September 30, 2014 is as follows:

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	Stock Option Activity under the Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2013	252,158	$4.80 — $248.64	$ 57.90	7.36
Granted	75,000	$2.42	2.42	
Forfeited	(80,399)	$4.80 — $248.64	62.11	
Expired	(22,166)	$19.84 — $62.40	56.39	
Outstanding at September 30, 2014	224,593	$4.80 — $245.12	$ 38.35	8.36

For the three and nine months ended September 30, 2014, the Company recognized compensation expense of approximately $0.1 million and $0.3 million, respectively, relating to stock options granted to employees. For the three and nine months ended September 30, 2013, the Company recognized compensation income of approximately $0.2 million and compensation expense of approximately $0.4 million, respectively. The compensation income for the three months ended September 30, 2013 is a result of the cancellation of stock options related to the Company's restructuring activities discussed further in Note 6 to these condensed consolidated financial statements.

There were 75,000 options granted during the nine months ended September 30, 2014. The estimated fair value of each option award granted during the nine month period ended September 30, 2014 and September 30, 2013 was determined on the date of grant using an option pricing model with the following assumptions:

	Nine months ended September 30,	
	2014	2013
Dividend yield	None	None
Expected volatility	98.14%	86.16% — 93.9%
Weighted average volatility	98.14%	86.37%
Risk-free interest rates	1.61%	0.99% — 1.79%
Expected life (in years)	4.5	6.7

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life of the stock options on the grant date. The expected option term is based on actual historical results.

Restricted stock activity for the nine months ended September 30, 2014 is as follows:

	Restricted Stock Activity under the Plans	
	Restricted Stock	Weighted Average Grant Date

		Fair Value
Non-vested at December 31, 2013	20,347	$ 16.84
Granted	62,504	2.60
Vested	(17,755)	49.68
Forfeited	(581)	14.06
Non-vested at September 30, 2014	64,515	$ 3.51

For the three and nine months ended September 30, 2014, the Company recognized compensation expense of approximately $0.04 million and $0.1 million, respectively, related to restricted stock granted to employees. For the three and nine months ended September 30, 2013, the Company recognized compensation income of approximately $0.1 million and compensation expense of approximately $0.2 million, respectively. The compensation income for the three months ended September 30, 2013 is a result of the cancellation of restricted stock related to the Company's restructuring activities discussed further in Note 6 to these condensed consolidated financial statements.

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(8) Fair Value Measurements

Derivative Warrant Liability

As disclosed in Note 7 Stockholders' Equity of these Condensed Consolidated Financial Statements, the Company allocated part of the proceeds of public offerings in 2009, 2012 and 2013 of the Company's common stock to warrants issued in connection with those transactions. The valuation of the warrants was determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrants should be classified as liabilities and has accounted for them as derivative instruments in accordance with ASC 815. 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 model 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 riskless 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 riskless 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 nine months ended September 30, 2014, the Company recorded pre-tax derivative warrant income of $0.5 million and $1.6 million, respectively. The resulting derivative warrant liabilities totaled $0.6 million at September 30, 2014. In the event of a hypothetical 10% increase in the market price of our common shares on which the September 30, 2014 valuation was based, the value of the derivative liability would have increased by approximately $0.1 million. Management expects that the warrants will either be exercised or expire worthless. The fair value of the warrants at September 30, 2014 was determined by using an option pricing model with the following assumptions:

	2013 Warrants	2012 Warrants
Expected volatility	90.32%	77.31%
Risk-free interest rates	1.43%	0.08%
Expected life (in years)	4.08	0.67

Money Market Funds

The Company has determined that the inputs associated with the fair value determination of its money market funds are based on quoted prices (unadjusted) and, as a result, the investments have been classified within Level 1 of the fair value hierarchy.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2014, aggregated by the level in the fair value hierarchy within which those measurements fall.

	Assets and Liabilities Measured at Fair Value

	on a Recurring Basis			
(in thousands)	Level 1	Level 2	Level 3	Balance at September 30, 2014
Assets				
Money market funds	$1,945	$ —	$—	$ 1,945
Liabilities				
Warrant liability	$—	$ —	$555	$ 555

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The table below presents the activity within Level 3 of the fair value hierarchy for the nine months ended September 30, 2014:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
(in thousands)	Warrant Liability
Beginning balance as of December 31, 2013	$ 2,310
Total change in the fair value of the liability included in earnings, including warrant expirations	(1,612)
Fair value of warrants exercised	(143)
Ending balance as of September 30, 2014	$ 555

(9) 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.

For the three and nine months ended September 30, 2014, basic and diluted net loss per common share are equal.

The following potentially dilutive securities were excluded from the computation of earnings per share as of September 30, 2014 and 2013 because their effects would be anti-dilutive:

	September 30,	
	2014	2013
Stock options	227,718	294,446
Unvested restricted shares	64,515	21,243
Warrants	850,138	339,994
Total	1,142,371	655,683

(10) 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. The Company has not been audited by the U.S. Internal Revenue Service, 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.

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(11) Commitment and Contingencies

The Company is a party to several legal proceedings. Refer to Part II, Item 1 Legal Proceedings in this Quarterly Report on Form 10-Q for more information.

(12) Subsequent Events

Subsequent to the end of the third quarter through November 4, 2014, the Company sold approximately 0.3 million shares of its common stock under the March 2013 Sales Agreement through an “at the market” equity offering program for net proceeds of approximately $0.4 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-187230). The net proceeds will be used for general corporate purposes, including, but not limited to, funding of the Company’s clinical trials, commercialization of our products, obtaining regulatory approvals, capital expenditures and working capital. As of November 4, 2014, the Company has approximately $40.0 million remaining under the program.

The Company completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no other subsequent events requiring disclosure in or adjustment to these financial statements.

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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, 2013 included in the Company's 2013 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 September 30, 2014 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," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q for the period ending September 30, 2014 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Quarterly Report on Form 10-Q for the period ended September 30, 2014 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, 2013 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;

the commencement of future clinical trials and the results and timing of those clinical trials;

our ability to successfully commercialize CHEMOSAT/Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and System;

the progress and results of our research and development programs;

submission and timing of applications for regulatory approval and approval thereof;

our ability to successfully source certain components of the system and enter into supplier contracts;

our ability to successfully manufacture CHEMOSAT/Melphalan/HDS;

our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and

our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this

Quarterly Report on Form 10-Q. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this report as well as Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's 2013 Annual Report on Form 10-K.

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Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary 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 the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic liver cancers.

In the United States (U.S.), Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for Generation Two CHEMOSAT. The right to affix the CE Mark allows the Company to market and sell CHEMOSAT in Europe. The Company has initiated plans to investigate Melphalan/HDS for several types of primary and metastatic cancers in the liver.

About CHEMOSAT/Melphalan/HDS
CHEMOSAT/Melphalan/HDS administer concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by first isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP), 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 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.

Treatment with CHEMOSAT/Melphalan/HDS
Currently there are few effective treatment options for cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. The most advanced application for which CHEMOSAT/Melphalan/HDS was evaluated is for the treatment of metastatic melanoma in the liver. During the Company’s clinical trials, the procedure typically took approximately two to three hours. Patients remained in the intensive care unit overnight for observation after undergoing treatment with CHEMOSAT/Melphalan/HDS. Treatment with the CHEMOSAT/Melphalan/HDS is a repeatable procedure, and during clinical trials patients received an average of three procedures at approximately four to eight week intervals. A new disposable CHEMOSAT/Melphalan/HDS system is used for each treatment.

Cancers in the Liver – A Significant Unmet Need
Cancers of the liver remain a major unmet medical need globally. According to GLOBOCAN and American Cancer Society (ACS) Facts & Figures 2008, approximately 1.2 million patients globally are diagnosed annually with primary liver cancer or cancer that has metastasized to the liver. 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. Chemosat/Melphalan/HDS is a proprietary product uniquely positioned to treat the entire liver either as a standalone therapy or complementary with other therapies.

Clinical Development Program

The focus of the Company’s Clinical Development Program (CDP) is to generate clinical data for the CHEMOSAT/Melphalan/HDS in various disease states, validate the safety profile of the current version of the product and treatment procedure, and address requirements contained in the FDA’s Complete Response Letter (CRL) issued in September 2013. The Company believes that the improvements to the Melphalan HDS and the changes to the medical procedures used during treatment have addressed the procedure-related risks found during the previous

Phase 1, 2, 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 U.S.

The Company is advancing plans to initiate a pivotal phase 3 overall survival (OS) clinical trial in ocular melanoma that is metastatic to the liver. Based on the strength of the efficacy data in this disease obtained in its original Phase 1, 2 and 3 program, and the reports of an improved safety profile from over 130 patient treatments performed in a non-clinical trial setting in Europe, the Company is confident that this program can address the concerns raised by the FDA in its CRL. The Company also believes that this Phase 3 program for OM offers the fastest path to resubmission of a new NDA seeking U.S. regulatory approval in ocular melanoma liver metastases.

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In 2014, the Company's efforts have been focused on initiating its Phase 2 clinical program to study CHEMOSAT/Melphalan/HDS for the treatment of hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC). Phase 2 trials for HCC are now open for enrollment in both Europe and the U.S. The Company has announced plans to expand the Phase 2 program for HCC to include an additional cohort of patients with ICC.

The Company is also supporting data generation in other areas. The Company plans to initiate a prospective registry in Europe to collect data from cases performed in a commercial setting by year-end. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers.

In addition to the prospective registry, the Company is also supporting two Investigator Initiated Trials (IITs) in Europe to further study CHEMOSAT in HCC and colorectal cancer metastasized to the liver (mCRC). The Company is considering supporting additional IITs as suitable opportunities present.

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.

Global Phase 3 Ocular Melanoma Trial

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally four to six months. According to the ACS and other international health agencies, approximately 8,600 cases of ocular melanoma are diagnosed annually in the U.S. and Europe, with more than half of these patients expected to develop liver metastases. Currently there is no standard of care for patients with ocular melanoma liver metastases.

The Company is planning to initiate a Global Phase 3 trial in ocular melanoma liver metastases, using overall survival (OS) as a primary endpoint. The Company will be working with the relevant Health Authorities in Europe and the U.S. with a view to initiating the trial in mid-2015. The Company believes that ocular melanoma liver metastases represent a high unmet medical need, and that pursuit of an indication in this disease state may be the fastest path to potential U.S. approval.

Hepatocellular Carcinoma (HCC) & Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers---including HCC and ICC---is one of the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 76,000 new cases of HCC are diagnosed in the U.S. and Europe annually. According to the ACS, the overall five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. 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 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 2013 outlines the treatment options for HCC as follows: "Early stage HCC can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Surgical treatment of early stage HCC is often limited by pre-existing liver

disease that has damaged the portion of the liver not affected by cancer. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor. Fewer treatment options exist for patients diagnosed at an advanced stage of the disease. Sorafenib (Nexavar) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery."

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers. Outside of resection which is the only cure for ICC, there is currently no standard of care (SOC).

Phase 2 Multi-Histology Clinical Trial - HCC Cohort

In the Company's multi-arm Phase 2 clinical trial---conducted between 2005 and 2010 and using an early version of the CHEMOSAT/Melphalan/HDS and treatment protocol---five patients with HCC were treated with CHEMOSAT/Melphalan/HDS in the primary hepatic malignancy cohort. 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 hepatic progression free survival (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, and we believe constitutes a promising signal that warrants further clinical investigation.

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Phase 2 HCC/ICC Program

The Company has initiated a new clinical trial program in Europe and the U.S., with the goal of obtaining an efficacy and safety signal for Melphalan/HDS in the treatment of HCC. Due to differences in treatment practice patterns between Europe and the U.S., the Company has established separate European and U.S. trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria. The U.S. trial will assess the safety and efficacy of Melphalan/HDS followed by sorafenib; the European trial will assess the safety and efficacy of Melphalan/HDS without sorafenib. Clinical observations from the two trials are designed to be complementary. The first center in Germany, Johannes Wolfgang Goethe University Frankfurt (JWG), opened for enrollment in July 2014. The Company intends to open additional centers in Germany and the U.K., subject to the applicable authorizations and approvals including ethics committee approval at participating hospitals. The Company has also announced an expansion of the European Phase 2 trial in HCC to include a cohort of patients with ICC. The trial for this cohort will be conducted at the same centers participating in the Phase 2 HCC trial, and is expected to be open for enrollment by the end of 2014. In the U.S., the Moffitt Cancer Center opened for enrollment in October 2014 and is expected to treat its first case prior to the end of 2014.

We anticipate data on the first eleven patients from both trials to be available in the first half of 2015, subject to timely enrollment of eligible patients. The Company is pursuing a staged clinical strategy HCC/ICC, starting with a Phase 2 clinical trial program followed by a Phase 3 trial if the initial responses from the Phase 2 study are positive.

European Clinical Data Generation

In addition, the Company plans to initiate a patient registry, which will prospectively collect data from the European commercial experience. The first hospital submitted the protocol to its Ethics Committee in January 2014 and, pending timely site participation, we anticipate the first site to be enrolling patients onto the registry during the second half of 2014. 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. Delcath intends to collect essential patient safety and efficacy information beginning with treatment centers in Germany. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. The Company believes the Patient Registry will provide valuable data and information from a commercial setting that can be used to support our efforts for clinical adoption and broad reimbursement in Europe.

European Investigator Initiated Trials

The Company is also presently supporting two IITs in Europe – one in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in The Netherlands, and another in HCC at JWG in Germany. Both of these trials have opened for enrollment. The Company expects to evaluate other IITs as suitable opportunities present in Europe. The Company believes IITs will serve to build clinical experience at key cancer centers, and will help support efforts to obtain full reimbursement in Europe.

Risks associated with CHEMOSAT/Melphalan/HDS
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. In Phase 1, 2, and 3 clinical trials using early versions of CHEMOSAT/Melphalan/HDS and treatment protocol, the integrated safety population of patients treated with CHEMOSAT/Melphalan/HDS showed these risks to include: a 4.1% incidence of deaths due to adverse reactions; 4% incidence of stroke; 2% incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment; a ≥ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week; and 8%

incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation. The trials that comprised this integrated safety population used early versions of CHEMOSAT/Melphalan/HDS, including the Generation One filter, and did not include use of the Generation Two filter or procedural revisions currently employed. In this integrated safety population, deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments.

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As a consequence of these identified risks and experience gained in non-clinical trial usage in Europe, Delcath has implemented further refinements to both the device and procedure. The procedure refinements have included modifications to the pre, peri and post procedure patient management and monitoring and 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.

Reports from treating physicians in both Europe and the U.S. using the CHEMOSAT/Melphalan/HDS in a non-clinical trial setting have suggested that these product improvements and procedure refinements have improved the safety profile. Collection of formal clinical data in a controlled trial environment on the current product configuration and associated safety profile is a primary objective of the Company's Enhanced Clinical Development Program. The Company believes that product and procedure improvements, together with comprehensive multidisciplinary training, the risks associated with the procedure can be managed by experienced clinicians.

In clinical development, the Expanded Access Program (EAP), compassionate use, and IITs, the Melphalan/HDS has been used to treat 179 patients. Two compassionate use patients and two EAP patients have received at least 5 cycles Melphalan/HDS. In Europe, in a commercial, non-clinical trial setting, the CHEMOSAT/Melphalan/HDS has been used to perform 134 treatments on 90 patients.

Regulatory Status

United States

In August 2012, we submitted our New Drug Application (NDA) for the Melblez Kit 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 we are seeking to ocular melanoma metastatic to the liver. The Company's NDA was accepted for filing by the Food and Drug Administration (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. The FDA's Oncologic Drugs Advisory Committee (ODAC) reviewed our NDA on May 2, 2013, and voted 16 to 0, with no abstentions, that the benefits of treatment with the Melblez Kit do not outweigh the risks associated with the procedure. Data submitted to the FDA used the early clinical trial versions of the system along with early clinical procedure techniques. On September 12, 2013, the FDA issued a Complete Response Letter (CRL) regarding the Company's NDA for Melblez Kit.

A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes 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 Melblez Kit using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melblez Kit outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. The Company held a meeting with FDA to clarify components of the CRL, during which it confirmed its understanding of device and procedure safety requirements contained in the CRL. We continue to believe that such an approval would meet a high unmet need in the U.S.

In the U.S., 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 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 (CDER) has primary jurisdiction over its pre-market development and review and the Company must pursue a new drug application pathway.

The process required by the FDA before drug product candidates may be marketed in the U.S. generally involves the following:

- submission to the FDA of an investigational new drug application, or 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;

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- 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 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 U.S..

Drug development and regulatory approval is an inherently uncertain process with a high risk of failure at every stage of development. 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 at all or on a timely basis.

Orphan Drug Exclusivity

Some jurisdictions, including the U.S., 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 U.S. The orphan designation is granted for a drug entity and a specific 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 five 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 orphan drug designation of the drug melphalan for the treatment of hepatocellular carcinoma.

The granting of orphan drug designation does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process which 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.

European Regulation

In the European Economic Area (EEA), CHEMOSAT is subject to regulation as a medical device. The EEA is composed of the 28 Member States of the European Union (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 CHEMOSAT are 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 CHEMOSAT 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.

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CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, a 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. In April 2012, the Company obtained authorization to affix a CE Mark for Generation Two CHEMOSAT.

Under the regulatory scheme in the EEA, the Company has received authorization to affix the CE Mark to CHEMOSAT as a device only, and physicians must separately obtain melphalan for use with CHEMOSAT. Our ability to market and promote CHEMOSAT is limited to this approved indication. Melphalan Hydrochloride for Injection is currently approved in 14 member states of the EEA, including the seven markets where procedures have been performed.

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 CHEMOSAT must obtain and use melphalan independently at their discretion.

Other International Regulations

CHEMOSAT 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. The Company will continue to evaluate commercial opportunities in these and other markets when resources are available and at an appropriate time.

European Sales and Marketing

With continued economic and reimbursement challenges in certain European markets, the Company's immediate market access and clinical adoptions efforts are focused on the key target markets of Germany and the United Kingdom, 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. The Company also continues to support clinical adoption of CHEMOSAT in the Netherlands, Italy, Spain and France. The Company uses a combination of direct and indirect sales channels to market and sell CHEMOSAT in Europe. In 2013, the Company utilized medical science liaisons through a third party to support our clinical adoption efforts. As part of the Company's restructuring, the medical science liaison consultant program has been phased out and we have integrated these capabilities into existing resources. To support our commercialization efforts in the EU, we have established our European Headquarters in Galway, Ireland.

Thus far in 2014 CHEMOSAT treatments have been performed in the United Kingdom, Germany, the Netherlands, France and Spain. During the nine months ending September 30, 2014 there were 59 CHEMOSAT treatments performed with 25 of these representing retreatments, compared to 27 CHEMOSAT treatments performed with eight

of these representing retreatments for the same period in the prior year. Since its February 2012 launch in Europe, CHEMOSAT has been used to perform 140 treatments on 94 patients.

Since launching CHEMOSAT in Europe, treatments have been performed at 18 leading European cancer centers, most recently at Medizinische Hochschule Hannover (MHH), Germany. 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 hepatocellular carcinoma, cholangeocarcinoma, and liver metastases from colorectal cancer, breast, and cutaneous melanoma.

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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. In 2013 the Company engaged a third party reimbursement specialist to support efforts in filing for reimbursement coverage. 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 January 2014, the Company announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, again granted Value 4 coverage status for the treatment of patients with liver metastases with CHEMOSAT. Under the Neue Untersuchungs und Behandlungsmethoden (NUB) reimbursement scheme, Value 4 Status, while not mandating reimbursement, allows participating cancer centers to negotiate a budget to fund reimbursement coverage for CHEMOSAT procedure with insurers serving their region.

The InEk determines three status levels for medical procedures submitted for its review: Value 1 (mandated reimbursement), Value 2 (declined for reimbursement), and Value 4 (negotiated reimbursement). The InEk may also decline to make a determination regarding an application. For 2014 reimbursement, a total of 618 medical procedures were submitted to the InEk for consideration under the NUB scheme, with 16% or 96 procedures receiving Value 1 Status, 6% or 36 procedures receiving Value 4, and the remaining 78% denied coverage or un-evaluated. The application for CHEMOSAT was submitted by 71 hospitals in Germany, which represents a significant increase in the level of institutional support the procedure received over 2013.

The InEk first established NUB Value 4 status for CHEMOSAT procedures in 2013, though we have been advised that hospitals did not successfully negotiate reimbursement budgets for CHEMOSAT in 2013. In 2014, we expect the process to be similar to 2013 and have been advised by several hospitals in Germany that they will focus their efforts primarily on NUB Value 1 negotiations rather than NUB 4 negotiations, and accordingly we do not expect there to be significant progress in obtaining reimbursement under NUB 4. The NUB is an annual process, and participating centers in Germany are required to apply each year for subsequent coverage under the NUB scheme. The 2015 NUB application was filed by the October 31, 2014 deadline.

The German Radiology Society resubmitted its application for ZE (Zusatzentgeld) for CHEMOSAT in March 2014, but this submission will not affect the relevant DRG codes in 2014. ZE is a national interim reimbursement code granted by the InEk until a specific DRG code can be created. A ZE code is dependent on having enough financial data related to the procedure to establish cost averages, and the Company’s efforts are focused on ensuring that treatment and cost data from specific hospitals are provided to the InEk to support a future ZE application.

Separately, throughout 2014, physicians and patients in Germany continue to submit and receive approval for Individual Funding Requests (IFRs) granting reimbursement for the treatment of liver metastases with CHEMOSAT. IFRs are case-by-case appeals for reimbursement made to the patient’s insurance carrier (“sickness funds”). While each IFR is evaluated independently, the majority of these applications have been approved this year. These approvals have covered a range of sickness funds across a number of regions in Germany including ocular melanoma, cutaneous

melanoma, intrahepatic cholangiocarcinoma, pancreatic cancer and sarcoma; and some were granted for multiple treatments of the same patients. We expect that IFRs will continue to be the key reimbursement vehicle in the German market for the remainder of 2014 and early 2015.

United Kingdom

In April 2013, interim funding for oncological procedures in the United Kingdom moved away from local Primary Care Trusts (PCTs) to a centralized body of cancer care commissioners. Delcath and its partner centers have identified existing Healthcare Resource Groups (HRG) code(s), which may allow hospitals to be covered for CHEMOSAT related costs. The Company is also working with the HRG organization that decides on new HRG codes with a view to gaining a dedicated and permanent reimbursement code in the future.

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The Company is also supporting efforts seeking a block fund grant through the Commissioning Through Evaluation (CTE) process which may provide up to 50-75 ocular melanoma patients to be treated utilizing CHEMOSAT in three centers across the U.K. It is important to note that the CTE process has been driven by partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. The British healthcare system continues to evolve however, and ongoing changes to the CTE process and funding streams have resulted in further delays and made the granting and timing of block funding difficult to predict. The current expectation is for the process to be completed by the end of the first quarter 2015 with the funding, if any, becoming available in the second quarter of 2015. The entire CTE funding mechanism is a new process and these ongoing policy changes in the National Health Service (NHS) make it difficult to predict the likelihood of success in the near term.

In December 2013, the National Institute for Clinical Excellence (NICE), a non-departmental public body that provides guidance and advice to improve health and social care in the UK, initiated a clinical review of CHEMOSAT. NICE issued provisional draft recommendations for the use of CHEMOSAT in the UK, and invited the Company as well as physicians and other interested parties to comment. The NICE recommendations were open for public comment until January 22, 2014, and a decision on final clinical recommendations was made on May 28, 2014 indicating that, as the current body of evidence on the safety and efficacy of chemosaturation via percutaneous hepatic artery perfusion 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. This may take the form of observational studies. With our anticipated Phase 2 HCC trial and the European Registry, 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.

Despite the NICE recommendations, public patients may continue to be treated in the UK through the Commissioning Through Evaluation (CTE) process or clinical trials. Private patients will continue to be treated through the established private treatment pathway.

Other European Markets

Permanent reimbursement coverage in remaining EU markets will require additional time to secure. In the interim period, the Company is seeking payment through various avenues, including new technology programs. In France, the Company has revised its strategy and decided not to pursue a multi-center STIC application. STIC is a hybrid of interim funding and clinical study, allowing a new procedure to be assessed over a two-year period on a pre-set number of treatments. The Company believes that the STIC process would be too time consuming and costly, and that direct pursuit of a DRG code represented a better allocation of Company resources in this market. The Company will also present its Phase 3 trial data, once published, to the French healthcare authorities in order to assess the possibility of gaining a DRG code without going through the STIC process.

For France and the Netherlands, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Company continues to work with the principal investigators on submission of its Phase 3 and Phase 2 clinical trials for publication. The timing of these submissions will be determined by the principal investigators and the Company looks forward to the submission of the publications.

Distribution Partners

As a result of the Company’s strategy to prioritize resources on the key direct markets of Germany 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. Similar to our strategy in Germany and the United Kingdom, the Company has decided to pursue a direct market approach through a contract sales consultant in Spain as opportunities present.

Management Transition

In September 2014, the Company announced the reorganization of the Company's leadership under which Dr. Jennifer Simpson was appointed interim President and CEO. Dr. Simpson served as interim Co-President and interim Co-CEO of Delcath since September 2013. Dr. Graham Miao, who had served as interim Co-President, interim Co-CEO and CFO, left the Company at the end of September to pursue other opportunities. Barbra Keck, Vice President, Controller & Principal Accounting Officer assumed the responsibilities of Principal Financial Officer. Dr. Roger G. Stoll, who has been a member of the Delcath Board of Directors since 2008, was appointed to the newly created position of Executive Chairman. He succeeds Gabriel Leung, who stepped down from his position as Chairman of the Board. Mr. Leung will remain on the Company’s Board.

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Material Modifications to Rights of Security Holders

On February 24, 2014, at a Special Meeting of Stockholders of Delcath Systems, Inc., the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock at a specific ratio within a range from one-for-eight (1:8) to one-for-sixteen (1:16), inclusive, on or prior to December 31, 2014 and granted authorization to the Company's Board of Directors to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing and ratio.

Following the approval by our stockholders, the Board approved a reverse stock split and on April 8, 2014, the Company, filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Amendment"), which effected a reverse stock split of its common stock at a ratio of 1-to-16 (the "Reverse Stock Split"). Trading of the Company's common stock on The NASDAQ Capital Market on a split-adjusted basis began at the opening of trading on April 9, 2014.

As a result of the Reverse Stock Split, each sixteen shares of common stock was combined into one share of common stock and the total number of shares of common stock outstanding was reduced from approximately 150.9 million shares to approximately 9.4 million shares. No fractional shares were issued if, as a result of the Reverse Stock Split, a registered stockholder was otherwise entitled to a fractional share. Instead, stockholders who were otherwise entitled to receive fractional shares because they held a number of shares not evenly divisible by the ratio of the Reverse Stock Split automatically received an additional share of common stock. In other words, any fractional share was rounded up to the nearest whole number.

On April 24, 2014, the Company received a notification letter from The NASDAQ Stock Market advising the Company that the closing bid price of the Company's common stock had been at $1.00 per share or greater for 10 consecutive business days, and accordingly, the Company had regained compliance with Listing Rule 5550(a)(2) and the matter was considered closed. The Company believes the reverse stock split was necessary in order to maintain the Company's listing on The NASDAQ Capital Market and to provide resources and flexibility with respect to capital sufficient to execute its business plans and strategy.

Results of Operations for the Three and Nine Months Ended September 30, 2014; Comparisons of Results of Operations for the Three and Nine Months Ended September 30, 2013

Three months ended September 30, 2014 and September 30, 2013

Revenue

The Company recorded approximately $0.2 million in revenue related to product sales during the three months ended September 30, 2014. The Company recorded approximately $0.1 million in revenue during the same period of 2013.

Cost of Goods Sold

During the three months ended September 30, 2014, the Company recorded cost of goods sold of approximately $50,000. During the same period in 2013, the Company recorded cost of goods sold of approximately $23,000. As Delcath continues progress with clinical adoption, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several years. This volatility will be related to several factors, including: adjustments to volume forecasts; the expected use of third party distributors whose purchase prices will be lower than direct-to-customer prices; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials,

labor and overhead; and an improvement in efficiencies as the Company increases its production of CHEMOSAT.

Selling, General and Administrative Expenses

For the three month periods ended September 30, 2014 and 2013, selling, general and administrative expenses were $4.5 million and $4.6 million, respectively. Included in these amounts are lease and workforce restructuring charges of $1.4 million in 2014 and workforce restructuring charges of $1.2 million in 2013. Excluding these restructuring charges, selling, general and administrative expenses were $3.1 million for the three months ended September 30, 2014 compared to $3.4 million for the three months ended September 30, 2013, a decrease of $0.3 million. The decrease in personnel and related expenses as a result of the Company's successful efforts to increase organizational efficiencies was offset by one-time expenses related to vacating the Company's offices at 810 Seventh Avenue, including contract termination costs and the write down of leasehold improvements.

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Research and Development Expenses

For the three month period ended September 30, 2014, research and development expenses were $0.7 million compared to $2.2 million for the three month period ended September 30, 2013, a decrease of $1.5 million. A significant portion of this decrease is related to the phasing out of the Company's medical science liaison program and the Company's successful efforts to increase organizational efficiencies.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the three months periods ended September 30, 2014 and 2013, the Company had interest income of approximately $2,000 and $2,000, respectively.

Other Expense and Interest Expense

Other expense is primarily related to foreign currency exchange gains and losses. Interest expense is related to an ongoing Revolving Line Facility Fee as required by the Loan and Security Agreement signed with Silicon Valley Bank in 2012 and discussed in Note 9 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K.

Net Loss

The Company recorded a net loss for the three months ended September 30, 2014, of $4.6 million, a decrease of $2.6 million, or 36.1%, compared to a net loss of $7.2 million for the same period in 2013. This decrease in net loss is primarily due to a $1.5 million reduction in operating expenses, a $0.1 million improvement in gross profit, and a $1.0 million favorable change in the fair value of the warrant liability, a non-cash item. As detailed above, the Company has reduced operating costs through workforce restructurings that began in 2013, reduced expenses related to its NDA submission and phased out its medical science liaison program.

Nine months ended September 30, 2014 and September 30, 2013

Revenue

The Company recorded approximately $0.8 million in revenue related to product sales during the nine months ended September 30, 2014 compared to approximately $0.2 million of product revenue and $0.3 million of previously deferred other revenue related to the Company's agreement with Chi-Fu Trading Co. Ltd. during the same period of 2013.

Cost of Goods Sold

During the nine months ended September 30, 2014, the Company recorded cost of goods sold of approximately $0.2 million. During the same period in 2013, the Company recorded cost of goods sold of approximately $0.4 million, which included the recognition of an inventory reserve of approximately $0.3 million. As Delcath continues progress with clinical adoption, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several years. This volatility will be related to several factors, including: adjustments to volume forecasts; the expected use of third party distributors whose purchase prices will be lower than direct-to-customer prices; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and

an improvement in efficiencies as the Company increases its production of CHEMOSAT.

Selling, General and Administrative Expenses

For the nine month periods ended September 30, 2014 and 2013, selling, general and administrative expenses were $13.0 million and $16.9 million, respectively. Included in these amounts are lease and workforce restructuring charges of $2.3 million in 2014 and workforce restructuring charges of $2.5 million in 2013. Excluding these restructuring charges, selling, general and administrative expenses were $10.7 million for the nine months ended September 30, 2014 compared to $14.4 million for the nine months ended September 30, 2013, a decrease of $3.7 million. A significant portion of this decrease is related to reduced personnel and related expenses as a result of the Company's 2013 workplace restructurings.

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Research and Development Expenses

For the nine month periods ended September 30, 2014 and 2013, research and development expenses were $3.6 million and $10.6 million, respectively. Included in these amounts are workforce restructuring charges of $0.6 million in 2014 and $0.2 million in 2013. Excluding these restructuring charges, research and development expenses were $3.0 million for the nine months ended September 30, 2014 compared to $10.4 million for the nine months ended September 30, 2013, a decrease of $7.4 million. A significant portion of this decrease is related to costs incurred for the Company's NDA submission to the FDA in 2013, the phasing out of the Company's medical science liaison program, and the Company's successful efforts to increase organizational efficiencies.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the nine months ended September 30, 2014, the Company had interest income of approximately $4,000 as compared to interest income of approximately $18,000 for the same period in 2013. The decrease in interest income was due to the combination of lower average daily cash balances in 2014 compared to 2013, and lower interest rates on those balances in 2014 compared to 2013.

Other Expense and Interest Expense

Other expense is primarily related to foreign currency exchange gains and losses. Interest expense is related to an ongoing Revolving Line Facility Fee as required by the Loan and Security Agreement signed with Silicon Valley Bank in 2012 and discussed in Note 9 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K.

Net Loss

The Company recorded a net loss for the nine months ended September 30, 2014, of $14.4 million, a decrease of $11.1 million, or 43.5%, compared to a net loss of $25.5 million for the same period in 2013. The decrease in net loss is primarily the result of an $11.0 million reduction in the Company's operating expenses and a $0.5 million improvement in gross profit. This was partially offset by a $0.75 million decline in derivative instrument income, a non-cash item. As detailed above, the Company has reduced operating costs through workforce restructurings that began in 2013, reduced expenses related to its NDA submission and phased out its medical science liaison program.

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 September 30, 2014, the Company had cash and cash equivalents totaling $23.3 million, as compared to cash, cash equivalents and certificates of deposit totaling $31.2 million and $27.7 million at December 31, 2013 and September

30, 2013, respectively. During the nine months ended September 30, 2014, the Company used $12.4 million of cash in its operating activities, which compares to $28.9 million used for operating activities during the comparable nine month period in 2013. The decrease of $16.5 million is primarily driven by a reduction in NDA submission related costs and improved efficiency in organization and operations. The Company believes that its capital resources are adequate to fund operations through the next twelve months.

Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fund its clinical development program or to fully commercialize the product. The Company continues to believe 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, 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 our 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 focus and direction of clinical trials, lower revenue and increased costs related to commercializing the product.

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The Company has funded its operations through a combination of private placements of its securities, public offerings in 2000, 2003, 2009, 2010, 2011, 2012 and 2013, registered direct offerings in 2007 and 2009, an "at the market" equity offering program initiated in 2012, and a committed equity financing facility program initiated in 2012. For a detailed discussion of the Company's various sales of securities and the "at the market" equity offering program see Note 7 to the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

In March 2013, the Company entered into a sales agreement (the "March 2013 Sales Agreement") with Cowen and Company, LLC to sell shares of the Company's common stock, par value $.01 per share, having aggregate sales proceeds of $50.0 million, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. During the nine months ended September 30, 2014, the Company sold approximately 1.0 million shares of its common stock under the March 2013 Sales Agreement with Cowen and Company, LLC for proceeds of approximately $4.4 million, with net cash proceeds after related expenses of approximately $4.4 million. The shares were issued pursuant to registration statement on Form S-3 (333-187230). The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital.

In December 2011, the Company filed a registration statement on Form S-3 with the SEC, which allowed the Company to offer and sell, from time to time in one or more offerings, up to $100 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deemed prudent or necessary to raise capital at a later date. The registration statement became effective on February 13, 2012. The Company used this registration statement for its May 2012 public offering detailed in Note 10 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K. The Company subsequently filed a new shelf registration statement on Form S-3 (333-183675) with the SEC which became effective on October 9, 2012. This new shelf replaces the shelf registration filed in December 2011 and allows the Company to offer and sell, from time to time in one or more offerings, up to $100 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company used this registration statement for its Common Stock Purchase Agreement with Terrapin Opportunity, L.P. detailed in Note 10 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K. As of September 30, 2014, Delcath had approximately $80.4 million available under this registration statement, of which approximately $4.8 million is reserved for the potential issuance of shares upon the exercise of warrants.

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 2013 Annual Report on Form 10-K. During 2012, Delcath transitioned from a development stage company to a commercial organization.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying ASC 740 management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

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ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. See Note 8 to the Company's Condensed Consolidated Financial Statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under ASC 820.

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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 June 2009, the Company completed the sale of 0.1 million shares of its common stock and the issuance of warrants to purchase 0.1 million common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's October 2013 sale of common stock and warrants. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the six months ended June 30, 2014, 35,000 2009 Warrants were exercised for net proceeds of $0.1 million. The 2009 Warrants had a five-year term which expired on June 15, 2014. The remaining liability after warrant exercises was credited to pre-tax derivative instrument income as of June 30, 2014.

In May 2012, the Company completed the sale of 1.0 million shares of its common stock and the issuance of warrants to purchase 0.3 million common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's October 2013 sale of common stock and warrants. At September 30, 2014, the 2012 Warrants were exercisable at $2.56 per share with 260,000 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the nine months ended September 30, 2014, 14,000 2012 Warrants were exercised for net proceeds of $34,000.

In October 2013, the Company completed the sale of 1.3 million shares of its common stock and the issuance of warrants to purchase 0.6 million 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 $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 Warrants. The 2013 Warrants became exercisable on April 30, 2014 and at September 30, 2014, the 2013 Warrants were exercisable at $7.04 per share with 0.6 million warrants outstanding. The 2013 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. There were no 2013 Warrants exercised during the nine months ended September 30, 2014.

The proceeds allocated to the 2009 Warrants, 2012 Warrants and 2013 Warrants were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As a result, for the three and nine month periods ended September 30, 2014, the Company recorded pre-tax derivative instrument income of $0.5 million and $1.6 million, respectively. The unexercised 2009 Warrants expired on June 15, 2014, while the fair value of the 2012 Warrants and 2013 Warrants totaled $0.6 million at September 30, 2014. Management expects that the warrants outstanding at September 30, 2014 will either be exercised or expire worthless. The fair value of the remaining Warrants at September 30, 2014 was determined by using an option pricing model assuming the following:

	2013 Warrants	2012 Warrants
Expected volatility	90.32%	77.31%
Risk-free interest rates	1.43%	0.08%
Expected life (in years)	4.08	0.67

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures
Delcath's management, with the participation of its Interim 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 Interim Chief Executive Officer concluded that Delcath's disclosure controls and procedures as of September 30, 2014 (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 Interim Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls
There was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2014 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

In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York (Case No. 13-cv-3116)

On May 8, 2013, a purported stockholder of the Company filed a putative class action complaint in the United States District Court for the Southern District of New York, captioned Bryan Green, individually and on behalf of all others similar situated, v. Delcath Systems, Inc., et al. ("Green"), Case No. 1:13-cv-03116-LGS. On June 14, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Joseph Connico, individually and on behalf of all others similarly situated, v. Delcath Systems, Inc., et al. ("Connico"), Case No. 1:13-cv-04131-LGS.

At a hearing on August 2, 2013, the Court consolidated the Green and Connico actions under the caption In re Delcath Systems, Inc. Securities Litigation, No. 13-cv-3116, appointed Lead Plaintiff, Delcath Investor Group, and approved Pomerantz Grossman Hufford Dahlstrom & Gross LLP as Lead Plaintiff's choice of counsel.

On September 18, 2013, Lead Plaintiff filed a consolidated amended complaint, naming the Company and Eamonn P. Hobbs as defendants (the "Defendants"). The consolidated amended complaint asserts that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by allegedly making false and misleading statements or omissions regarding the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma in the liver. The putative class period alleged in the amended complaint is April 21, 2010 through and including September 13, 2013. Lead Plaintiff seeks compensatory damages, equitable relief, and reasonable attorneys' fees, expert fees and other costs. On October 31, 2013, Defendants filed their motion to dismiss, which was subsequently denied on June 27, 2014. On July 25, 2014, Defendants filed their respective answers to Lead Plaintiff's consolidated amended complaint. On July 29, 2014, the Court held a scheduling conference setting forth a case management plan. The parties are proceeding with discovery. On October 15, 2014, Lead Plaintiff served Defendants with a Motion for Class Certification. Defendants anticipate serving a response to this Motion by November 25, 2014.

The Company believes that the In re Delcath Systems, Inc. Securities Litigation action lacks merit and intends to defend the case vigorously.

In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS)

On May 23, 2013, purported stockholders of the Company filed a shareholder derivative lawsuit in the United States District Court for the Southern District of New York, captioned Vincent J. Orlando and Carol Orlando, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Orlando"), Case No. 1:13-cv-03494-LGS. On June 11, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Howard Warsett, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Warsett"), Case No. 1:13-cv-04002-LGS. On July 19, 2013, another substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Patricia Griesi, derivative on behalf of nominal defendant Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Griesi"), Case No. 13 cv 5024. In all three cases, Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung were named as defendants (the"Individual Defendants"), and the Company

was named as a nominal defendant.

All three complaints assert claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, and gross mismanagement for making false and misleading statements or failing to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. In addition, the Orlando complaint further asserts claims for contribution and indemnification, abuse of control, and waste of corporate assets, while the Warsett complaint asserts an additional claim for unjust enrichment. The Griesi complaint also asserts additional claims for breach of fiduciary duties for failing to maintain internal controls, unjust enrichment, abuse of control, and violations of Section 14(a) of the Securities Exchange Act of 1934. The relevant time period alleged in the Orlando action is April 21, 2010 through the present, and the relevant time period alleged in the Warsett action is April 10, 2010 through the present. The relevant time period alleged in Griesi is April 21, 2010 through May 2, 2013. The Orlando, Warsett, and Griesi plaintiffs seek damages as well as reasonable costs and attorneys' fees. The Griesi plaintiffs also seek corporate governance reforms and improvements and restitution.

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DELCATH SYSTEMS, INC.

On June 25, 2013, the Court consolidated the Orlando and Warsett actions with the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS ("Consolidated Derivative Case"). On August 1, 2013, the Court consolidated the Griesi action under the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS. At a hearing on August 2, 2013, the Court entered an order approving Federman & Sherwood as lead counsel. The Court stayed the Consolidated Derivative Case, pending resolution of an anticipated motion to dismiss in In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York, No. 13-cv-3116.

On September 12, 2014, Plaintiffs Vincent Orlando and Carol Orlando filed a Verified Amended Consolidated Shareholder Derivative Complaint (the "Amended Complaint") in the Consolidated Derivative Case. The Amended Complaint is brought against the Individual Defendants, and names the Company as a nominal defendant (collectively, the "Defendants"). The Amended Complaint alleges breaches of fiduciary duty against the Individual Defendants for disseminating false and misleading information and for failing to properly oversee and manage the company. In addition, the Amended Complaint alleges claims for gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets. The relevant time period alleged in the Amended Complaint is April 21, 2010 through the present. The Plaintiffs in the Amended Complaint seek damages as well as reasonable costs and attorneys' fees. On October 27, 2014, Defendants served Plaintiffs with their Motion to Dismiss the Amended Complaint.

The Individual Defendants in the Consolidated Derivative Case deny any wrongdoing, believe the claims are baseless, and will defend accordingly.

Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., Supreme Court of the State of New York County of New York (Case No. 652030/2013)

On June 7, 2013, a purported stockholder of the Company filed a shareholder derivative lawsuit in the Supreme Court of the State of New York County of New York, captioned Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., ("Weinstein") Case No. 652030/2013. The action named Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung as individual defendants (the "Individual Defendants"), as well as the Company, as a nominal defendant.

The complaint asserts claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets in connection with allegations that the Individual Defendants made false and misleading statements or failed to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. The relevant time period alleged is April 21, 2010 through the present. The plaintiff seeks damages, as well as reasonable costs and attorneys' fees.

In July 2014, the parties in the Weinstein matter agreed to stipulate to stay the proceeding until the federal district court rules on the anticipated motion to dismiss in In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS).

The Individual Defendants in the Weinstein matter deny any wrongdoing, believe the claims are baseless, and will defend accordingly.

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DELCATH SYSTEMS, INC.

Item 1A. Risk Factors

Delcath's 2013 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

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

Not Applicable.

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DELCATH SYSTEMS, INC.

Item 6. Exhibits

Exhibit No.		Description
10.1	(1)	Agreement of Lease dated February 5, 2010 and Lease Modification, Extension and Additional Space Agreement dated September 27, 2010
10.2	(2)	Sublease Agreement between Delcath Systems, Inc. and SLG 810 Seventh Lessee LLC, dated May 22, 2014
10.3	(3)	Sublease Agreement between Delcath Systems, Inc. and ICV Partners, LLC dated August 18, 2014
10.4	(3)	License Agreement between Delcath Systems, Inc. and Dresdner Kleinwort Group Holdings, LLC dated September 23, 2014
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.
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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 an Exhibit to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on May 5, 2010 and incorporated herein by reference.

(2)

Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on May 28, 2014 and incorporated herein by reference.

(3) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on September 30, 2014 and incorporated herein 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.

November 5, 2014 DELCATH SYSTEMS, INC.
(Registrant)

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

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