DELCATH SYSTEMS INC
Form 10-Q
May 09, 2012

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 March 31, 2012.

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.)

810 Seventh Avenue, Suite 3505, New York, New York 10019
(Address of principal executive offices)

(212) 489-2100
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes 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 x
Non-accelerated filer o (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 May 8, 2012, 50,159,859 shares of the Company's common stock, $0.01 par value were outstanding.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Index to Financial Statements

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	March 31, 2012	December 31, 2011
Assets:		
Current assets		
Cash and cash equivalents	$ 17,050	$ 25,777
Investments – Certificates of deposit	3,735	4,980
Prepaid expenses and other current assets	1,345	1,231
Total current assets	22,130	31,988
Property, plant and equipment		
Land	154	154
Furniture and fixtures	904	880
Machinery and equipment	1,424	1,371
Computer software and equipment	1,469	1,212
Leasehold improvements	1,386	1,148
	5,337	4,765
Less: accumulated depreciation	(1,834)	(1,512)
Property, plant and equipment, net	3,503	3,253
Total assets	$ 25,633	$ 35,241
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 1,802	$ 925
Accrued expenses	3,824	5,473
Warrant liability	2,930	2,439
Total current liabilities	8,556	8,837
Deferred revenue	300	300
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2012 and December 31, 2011	–	–
Common stock, $.01 par value; 70,000,000 shares authorized; 49,788,761 and 48,237,630 shares issued and 49,760,661 and 48,209,534 outstanding at March 31, 2012 and December 31, 2011, respectively	498	482
Additional paid-in capital	178,159	172,613
Deficit accumulated during the development stage	(161,829)	(146,940)
Treasury stock, at cost; 28,100 shares at March 31, 2012 and December 31, 2011	(51)	(51)
Total stockholders' equity	16,777	26,104
Total liabilities and stockholders' equity	$ 25,633	$ 35,241

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

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

	Three months ended March 31,		Cumulative from inception (August 5, 1988) To March 31,
	2012	2011	2012
Costs and expenses			
General and administrative expenses	$7,423	$4,166	$ 68,571
Research and development costs	7,131	3,648	88,894
Total costs and expenses	14,554	7,814	157,465
Operating loss	(14,554)	(7,814)	(157,465)
Change in fair value of warrant liability, net	(338)	5,966	(5,471)
Interest income	3	-	2,880
Other expense and interest expense	-	-	(274)
Net loss	$(14,889)	$(1,848)	$ (160,330)
Common share data:			
Basic and diluted loss per share	$(0.31)	$(0.04)	
Weighted average number of basic and diluted common shares outstanding	48,341,670	42,953,553	
Comprehensive loss	$(14,889)	$(1,856)	$ (160,376)

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands, except share data)

	Three months ended March 31,		Cumulative from inception (August 5, 1988) to March 31,
	2012	2011	2012
Cash flows from operating activities:			
Net loss	$(14,889)	$(1,848)	$ (160,330)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	703	1,188	15,086
Restricted stock and warrant compensation expense	230	105	4,439
Depreciation expense	322	216	1,888
Amortization of organization costs and loss on disposal of equipment	-	-	52
Warrant liability fair value adjustment	338	(5,966)	5,471
Non-cash interest income	(3)	-	(14)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other current assets	(111)	490	(1,339)
Decrease in investment in common stock	-	-	46
Increase (decrease) in accounts payable and accrued expenses	(772)	(908)	5,627
Deferred revenue	-	-	300
Net cash used in operating activities	(14,182)	(6,723)	(128,774)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(572)	(1,249)	(5,402)
Purchase of short-term investments and marketable equity securities	(1,743)	-	(51,415)
Proceeds from maturities of short-term investments	2,988	1,492	47,642
Organization costs	-	-	(42)
Net cash provided by (used in) investing activities	673	243	(9,217)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	4,782	144	153,887
Repurchases of common stock	-	-	(51)
Dividends paid on preferred stock	-	-	(500)
Proceeds from short-term borrowings	-	-	1,705
Net cash provided by financing activities	4,782	144	155,041
(Decrease) increase in cash and cash equivalents	(8,727)	(6,336)	17,050
Cash and cash equivalents at beginning of period	25,777	45,621	-
Cash and cash equivalents at end of period	$17,050	$39,285	$ 17,050
Supplemental cash flow information:			
Cash paid for interest	$-	$-	$ 171
Supplemental non-cash activities:			
	$-	$184	$ 1,245

Cashless exercise of stock options and shares surrendered upon restricted stock vesting			
Fair value of warrants issued	$153	$-	$ 6,612
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$-	$9,154	$ 9,154

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Consolidated Financial Statements
for the Three Months Ended March 31, 2012 and 2011
and Cumulative from Inception (August 5, 1988) to March 31, 2012

Note 1: Description of Business and Summary of Significant Accounting Policies

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath announced that its randomized Phase III clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® delivery system in April 2011 and in April 2012, the Company announced it had received CE Mark approval for the second generation hemofiltration cartridge of the Hepatic CHEMOSAT Delivery System. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company continues with the preparation of its NDA submission and intends to seek FDA approval for commercial sale of its chemosaturation system with melphalan hydrochloride, or melphalan.

The Company has incurred losses since inception and has a deficit accumulated during the development stage of $161.8 million as of March 31, 2012. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management 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, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

Basis of Condensed Consolidated Financial Statement Presentation and Use of Estimates
The accompanying 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 instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company’s condensed consolidated financial statements. The condensed consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company’s condensed consolidated balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, income taxes and research and development costs. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates. The unaudited interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company’s results of operations, financial position

and cash flows for the interim periods ended March 31, 2012 and 2011, and cumulative from inception (August 5, 1988) to March 31, 2012.

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The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2011, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 as filed with the Securities and Exchange Commission (the "SEC") on March 6, 2012.

Research and Development Costs
Research and development costs include the costs of materials, personnel, outside services and applicable indirect costs incurred in development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

General and Administrative Costs
General and administrative costs include salaries and related expenses for the Company's executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Deferred Revenue Recognition
Deferred revenue on the accompanying condensed consolidated balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. The Company will amortize deferred revenue over the expected obligation period of the agreement once this amount is reasonably determinable.

Note 2: Recently Adopted Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04 which was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05 which provides new guidance on the presentation of comprehensive income. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and instead requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The adoption of this ASU only requires a change in the format of the current presentation. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's condensed consolidated financial statements.

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In December 2011, the Financial Accounting Standards Board ("FASB") issued ASU 2011-12, "Comprehensive Income". This update amends certain pending paragraphs in ASU No. 2011-05 "Presentation of Comprehensive Income", to effectively defer only those changes that relate to the presentation of reclassification adjustments out of accumulated other comprehensive income for annual and interim financial statements for public, private, and non-profit entities. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's condensed consolidated financial statements.

Note 3: Stock Option Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000, and 4,200,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. 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. 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 and conditions of each award, the option price and the duration of each award.

During 2004 and 2009, respectively, the 2004 and 2009 Stock Incentive Plans became effective. 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 three month period ended March 31, 2012 is as follows:

	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, 2011	4,129,749	$1.23-$15.54	$ 5.09	6.38
Granted	941,030	$3.09-$4.60	$ 4.35	
Forfeited	(22,468)	$2.26-$6.42	$ 2.94	
Outstanding at March 31, 2012	5,048,311	$1.23-$15.54	$ 4.96	6.82

For the three months ended March 31, 2012, the Company recognized compensation expense of approximately $0.5 million relating to options granted in previous years and $0.2 million relating to options granted during 2012.

The Company uses an option pricing model to determine the fair value of stock options awarded to employees on the date of grant. The Company has expensed its stock-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company accounts for stock-based compensation expense for non-employees using the fair-value method which requires the award to be re-measured at each reporting date until the award is vested. The Company estimates the fair value using an option pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

The assumptions used in the option pricing model to determine the fair value of stock options awarded to employees are as follows:

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	Three Months Ended March 31,	
	2012	2011
Dividend yield	None	None
Expected volatility	77.37% - 79.24 %	73.90% - 74.70 %
Weighted average volatility	78.75 %	74.26 %
Risk-free interest rates	1.03% – 1.49 %	2.29% - 2.54 %
Expected life (in years)	6.0	6.0

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock. 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 holding period was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under FASB ASC 718. This method of determining the expected holding period was utilized because the Company does not have sufficient historical experience from which to estimate the period.

Restricted stock activity for the three month period ended March 31, 2012 is as follows:

	Restricted Stock Activity under the Plans		
	Restricted Stock	Exercise Price per Share	Weighted Average Exercise Price
Outstanding at December 31, 2011	823,920	$ 1.26 - $12.34	$ 5.05
Granted	191,650	$ 3.09 - $4.60	$ 4.42
Forfeited	(4,334)	$ 2.26 - $6.42	$ 2.58
Outstanding at March 31, 2012	1,011,236	$ 1.26 - $12.34	$ 4.93

For the three months ended March 31, 2012, the Company recognized compensation expense of $0.2 million relating to restricted stock granted in previous years. For the three months ended March 31, 2012, the Company recognized approximately $50,000 relating to restricted stock granted during 2012.

Note 4: Assets and Liabilities Measured at Fair Value

Derivative warrant liability

The Company allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is 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 warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the 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 FASB ASC 820-10-35. There are six inputs: the closing price of the Company's common 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 our historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (820-10-35-40). The riskless rate of return is a Level 2 input as defined in FASB ASC 820-10-35-48, while the historical volatility is a Level 3 input as defined in FASB ASC 820-10-55-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

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In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of those proceeds to the 2007 Warrants (see below). The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and will expire on September 21, 2012. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock and were further adjusted following the Company's March 19, 2012 sale of common stock under the "at the market" equity offering program as discussed in more detail in Note 5 of this filing. At March 31, 2012, the 2007 Warrants were exercisable at $3.03 per share with 1,668,298 warrants outstanding. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross 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 (see below). As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's March 19, 2012 sale of common stock under the "at the market" equity offering program as discussed in more detail in Note 5 of this filing. As of March 31, 2012, the 2009 Warrants were exercisable at $3.03 per share with 1,043,478 warrants outstanding. The 2009 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

The $2.2 million in proceeds allocated to the 2009 Warrants and the $4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2012, the Company recorded pre-tax derivative instrument expense of $0.3 million. The resulting derivative instrument liabilities totaled $2.9 million at March 31, 2012. Management expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative instrument liabilities will be credited to stockholders' equity. The fair value of the Warrants at March 31, 2012 was determined by using an option pricing model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.14% for the 2007 Warrants, volatility of 82.83% for the 2009 Warrants and 90.74% for the 2007 Warrants and an expected life equal to the contractual life of the warrants (June 2014 and September 2012, respectively).

Money Market Funds

Cash and cash equivalents includes a money market account valued at $16.7 million. The fair market value of certificates of deposit at March 31, 2012 was $3.7 million.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2012, aggregated by the level in the fair value hierarchy within which those measurements fall:

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Assets and Liabilities Measured at Fair Value on a Recurring Basis at March 31, 2012
(in thousands)

	Level 1	Level 2	Level 3	Balance at March 31, 2012
Assets				
Money market funds	$ 16,712			$ 16,712
Total Assets	$ 16,712			$ 16,712
Liabilities				
Warrant liability			$ 2,930	$ 2,930
Total Liabilities			$ 2,930	$ 2,930

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
(in thousands)

	Warrant Liability
Beginning balance	$ 2,439
Total increase in the liability included in earnings	338
Fair value of warrants issued	153
Ending balance	$ 2,930

Note 5:Common Stock

On December 29, 2011, the Company entered into a sales agreement (the “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 $39,750,000, from time to time, through an “at the market” equity offering program under which Cowen and Company, LLC will act as sales agent. As of March 31, 2012, the Company had sold approximately 1.4 million shares of its common stock through the program for net proceeds of approximately $4.8 million. The net proceeds were 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. As discussed in more detail in Note 4 of this filing, these issuances triggered an adjustment of the exercise price and number of warrant shares under the Company’s outstanding warrant agreements. As of March 31, 2012, there was approximately $34.8 million available under this program, assuming sufficient shares are available to be issued.

Note 6:Net Loss

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options and warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at March 31, 2012 and 2011 upon exercise or conversion that were not included in the computation of net loss per share totaled 7,760,087 and 6,653,565 shares, respectively.

Note 7: Taxes

As discussed in Note 4 to the Company’s audited financial statements contained in the 2011 Annual Report on Form 10-K, 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.

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The Company is subject to income tax in the United States, the Republic of Ireland, and certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS"), international tax authorities, or any states in connection with income taxes. The periods from December 31, 2004 to December 31, 2011 remain open to examination by the IRS and state authorities. The period ending December 31, 2011 remains open to examination by the international authorities. Also note that the federal, state and international 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.

For the three months ended March 31, 2012, the Company recorded a state capital tax benefit of $62,500. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to $250,000 per year. Since this is not an income tax benefit, it is reflected as a component of general and administrative expenses.

Note 8:Subsequent Events

During the second quarter through May 8, 2012, the Company sold approximately 395,000 shares of our common stock under the Sales Agreement for net proceeds of approximately $1.1 million. These issuances triggered an adjustment of the exercise price and number of warrant shares under the Company's outstanding warrants, as a result of which, as of April 23, 2012 the 2007 Warrants are exercisable at $2.65 per share with 1.9 million warrants outstanding and the 2009 Warrants are exercisable at $2.65 with 1.0 million warrants outstanding. 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. As of May 8, 2012, the Company has approximately $33.6 million remaining under the program, assuming sufficient shares are available to be issued.

On April 5, 2012 the Company announced it had received CE Mark approval for the second generation hemofiltration cartridge of the Company's proprietary Hepatic CHEMOSAT® Delivery System. With the new hemofiltration cartridge, the CHEMOSAT system carries the same broad indication as the previous generation system, permitting physicians to use the product for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver to any patient who in their opinion may benefit.

On April 20, 2012, the Company entered into a four-year Loan and Security Agreement (the "Credit Agreement") with Silicon Valley Bank ("SVB"), as lender. The Credit Agreement consists of a revolving credit facility in an amount equal to the lesser of $20,000,000 and the Company's Borrowing Base (as defined in the Credit Agreement). In order to draw down on the facility, the Company will need to have at least the greater of (i) $15,000,000 in cash and cash equivalents in its account with SVB plus the amount of all outstanding obligations of the Company owed to SVB and (ii) trailing 3 months Cash Burn (as defined in the Credit Agreement) plus the amount of all outstanding obligations of the Company owed to SVB.

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

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, 2011 included in the Companys' 2011 Annual Report on Form 10-K to provide an understanding of its results of operations, financial condition and cash flows.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to Delcath's business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "s "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these ter comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Exchange 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 the Company's Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in this report under "Risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

- the progress and results of the Company's research and development programs;
- the Company's estimates regarding sufficiency of cash resources, anticipated capital requirements and need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- the Company's ability to successfully source certain components of the system and enter into supplier contracts;
- the Company's ability to successfully manufacture and commercialize the Delcath chemosaturation system; and
- the Company's ability to successfully negotiate and enter into agreements with strategic and corporate partners.

Many of the important factors that will determine these results are beyond the Company's ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements contained in this Quarterly Report on Form 10-Q, which speak only as of the date of this report. 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 and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K.

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and

other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath announced that its randomized Phase III clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT System) in April 2011 and in April 2012, the Company announced it had received CE Mark approval for the second generation hemofiltration cartridge of the CHEMOSAT System. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT System in Europe. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company continues with the preparation of its NDA submission and intends to seek FDA approval for commercial sale of its chemosaturation system with melphalan.

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The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapeutic agents directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The Delcath chemosaturation system involves a series of three catheter insertions, each of which is placed percutaneously through standard interventional radiology techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs and the potential for concomitant cancer therapies. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

European Market Commercialization

In April 2011, the Company obtained the right to affix the CE Mark to the first generation CHEMOSAT System. The right to affix the CE mark allows Delcath to market and sell the CHEMOSAT System in the European Economic Area (EEA). In the EEA, the CHEMOSAT System is regulated as a medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return. In April 2012, the Company announced it received CE Mark approval for the second generation hemofiltration cartridge of the Company's CHEMOSAT System. The second generation system has demonstrated filter efficiency greater than 98% during drug infusion of melphalan in an in vivo study; the same study also showed that the Generation 2 filter removes fewer blood platelets. The second generation filter is already in use at the European Institue of Oncology (IEO), with the first patient having been treated in April.

In March 2012, Delcath announced that it had received its first commercial order for the Company's CHEMOSAT System from the IEO. This order was fulfilled with second generation systems in April 2012 following the receipt of the CE Mark approval for the second generation hemofiltration cartridge.

Delcath believes the CHEMOSAT System may ultimately fulfill an annual unmet clinical need for as many as 59,000 liver cancer patients in the EEA. The Company intends to focus its initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. Delcath believes these countries represent a majority of the total potential liver cancer market in EEA countries and plans to use a combination of direct and indirect sales channels to market and distribute the CHEMOSAT System in the EEA. Delcath’s European commercialization strategy involves the establishment of clinical training and centers of excellence to educate and train physicians in these countries in order to develop key opinion thought leadership and foster initial market acceptance. To support its commercialization efforts in the EEA, the Company has established its European Headquarters in Galway, Ireland.

In 2011, the Company announced that it had entered into its first initial training and marketing agreement with the European Institute of Oncology in Milan, Italy. Since then, the Company has entered into eight additional initial launch and training agreements with leading European cancer centers, and has established a presence in five of the seven target markets. In February 2012, the first European patient treatments with the generation one CHEMOSAT System took place at IEO in Italy and Frankfurt University Hospital in Germany. The initial patients involved were treated for inoperable liver-dominant metastases from ocular melanoma, cutaneous melanoma, breast cancer and gastric cancer.

Regulatory

International Regulations

Having obtained the CE Mark for the CHEMOSAT System, the Company believes the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the EEA and the United States. Delcath recently received regulatory approval for the CHEMOSAT System in Australia and completed the product notification process in New Zealand, where the Company expects to launch the CHEMOSAT System in the second half of 2012 through authorized distributors. The Company has submitted applications for regulatory approval as a device for the CHEMOSAT System in Hong Kong, South Korea, and Singapore and intends to submit regulatory applications in Israel, Canada, Mexico, Argentina, Brazil, Russia, India, Japan, China, and Taiwan. Delcath is in the process of determining the regulatory pathway in some of these countries subject to negotiations with the applicable health authority. It is Delcath's intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath CHEMOSAT System, where appropriate. Delcath Systems Limited's facility in Galway, Ireland has obtained certificates of free sale from the Irish Medicines Board as many markets require country of origin manufacturing, such as Mexico, Argentina, Brazil, Japan, China, and Taiwan, as a prerequisite to obtain regulatory approval.

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United States

In the United States, the Delcath chemosaturation system for the administration of melphalan hydrochloride is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration (FDA). In December 2010, the Company submitted its Section 505(b)(2) New Drug Application (NDA), to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, Delcath received a Refusal to File (RTF) letter from the FDA for the NDA. The FDA will issue an RTF if it determines, upon an initial review, that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. On January 12, 2012, we held a pre-NDA meeting with the FDA to discuss our NDA submission and provide an update on the items identified in the RTF. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission.

The very substantive work of clinical and safety data gathering from all of the clinical sites and the migration to FDA compliant clinical and safety databases is now complete and the Company is in the final stages of preparing its NDA submission. The last remaining task before the database is locked is resolution of a relatively small number of outstanding database queries at each site. Queries are routine questions about individual patient data records in an effort to complete a final reconciliation of the data. This task will be concluded on May 25th, at which point the database will be locked. Immediately after this, a final statistical analysis will be conducted and the final NDA submission package will be completed. We expect these final steps to take approximately 10 weeks to complete following the May 25th database lock, putting submission of the NDA in mid-August. The database lock is also important with respect to publications. Once the database is locked, the primary investigators will have the complete information needed to incorporate the data for the Phase 3 trial and multi-arm Phase 2 trials into their manuscripts and then submit them for publication.

In addition to the ongoing work on the NDA submission, the Company believes that it is in the best interest of patients to explore ways of accelerating the availability of its Generation 2 product to patients in the United States and therefore has submitted to the FDA an amendment to its Investigational New Drug application to include Generation 2 in the FDA's expanded access program, as well as all future clinical trials and compassionate use cases. Additionally, the Company has initiated dialogue with the FDA to discuss the optimal approval path for Generation 2 in the United States. From these discussions, the Company hopes to gain insight to ensure that its NDA submission is prepared in the best possible manner to support a future Generation 2 NDA supplement, which would be filed after the Generation 1 NDA is approved.

Results of Operations

Since its inception, the Company has raised approximately $153.9 million (net of fundraising expenses), primarily through public and private placements of equity securities. The Company has incurred net losses since it was founded and expects to continue to incur significant and increasing net losses over the year. Although the Company expects that the amount of capital required for operations including preparation of the Company's submission to the FDA, operations at the manufacturing facility in upstate New York, and efforts to commercialize the CHEMOSAT System in Europe will continue to increase over the coming months, the Company believes that it has access to sufficient capital for operations through 2012.

Three Months Ended March 31, 2012 and March 31, 2011

Delcath has operated at a loss for its entire history. The Company had a net loss for the three months ended March 31, 2012, of $14.9 million, which is a $13.0 million increase in the net loss for the same period in 2011. The increase in net loss is due to an increase of $6.7 million in total costs and a $6.3 million change in the fair value of the warrant liability.

The Company's operating loss for the three months ended March 31, 2012 was $14.6 million, of which $0.9 million is non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans as discussed in more detail in Note 3 of this filing. This compares to an operating loss for the three months ended March 31, 2011 of $7.8 million, of which $1.3 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

At the end of the first quarter of 2012 the Company had 93 full-time employees compared to 50 at the end of the first quarter of 2011. The increase in total costs is commensurate with this growth, which has led to an increase in payroll and overhead expenses. Additionally, the Company's ongoing commercialization efforts in the European Union, continued efforts to prepare its submission to the FDA, as well as research and development activities, such as the recently approved Generation 2 filter, have contributed to the increase in total costs and expenses. As the Company continues to advance its business strategy, it will continue to incur losses for the forseeable future.

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For the three months ended March, 31 2012, general and administrative expenses increased to $7.4 million from $4.2 million for the three months ended March 31, 2011. A significant portion of the increase is related to the Company's continued expansion, particularly as Delcath has continued executing on its commercialization plans by hiring staff for the EU headquarters in Galway, Ireland and for sales and marketing support positions across Europe. This has led to an increase in personnel-related expenses, as well as all other expenses related to maintaining offices and supporting employees.

For the three months ended March 31, 2012, research and development expenses increased to $7.1 million from $3.6 million for the three months ended March 31, 2011. The increase in expenses is primarily related to the global regulatory efforts including continued preparation of the NDA submisson to the FDA, securing CE Mark for the Generation 2 filter and the expansion of addressable markets through the pursuit of additional regional regulatory approvals.

Interest income is from a money market account and certificates of deposit. During the three months ended March 31, 2012, the Company had interest income of $3,234, as compared to $559 for the same period in 2011.

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 year. 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 operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of 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. The Company continues to move forward aggressively. As Delcath launches commercial sales and marketing activity in Europe and seeks FDA approval of the Delcath chemosaturation system in the U.S., the Company expects that both expenses and capital expenditures will increase.

At March 31, 2012, the Company had cash, cash equivalents and certificates of deposit totaling $20.8 million, as compared to $39.3 million at March 31, 2011. During the three months ended March 31, 2012, the Company used $14.2 million of cash in its operating activities, which compares to $6.7 million used for operating activities during the comparable three month period in 2011. The increase of $7.5 million is primarily driven by NDA submission related costs, an increase in compensation related expenses as the Company grew from 50 employees at March 31, 2011 to 93 employees at March 31, 2012, expenses related to the Company's ongoing commercialization efforts in the EEA, and research & development activities, such as the recently approved Generation 2 filter. The Company expects that cash allocated to operating activities will continue to increase as it aggressively moves forward with commercialization plans for Europe and incurs regulatory expenses related to its submission to the FDA. The Company believes it has access to sufficient capital to fund operating activities through 2012.

At March 31, 2012, the Company's accumulated deficit was approximately $161.8 million. Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fully commercialize the product or to fund development efforts relating to additional indications. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, 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 and 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 and 2011, registered direct offerings in 2007 and 2009, and an “at the market” equity offering program. For a detailed discussion of the Company’s various sales of securities and the “at the market” equity offering program see Note 3 to the Company’s audited financial statements contained in the 2011 consolidated financial statements in the 2011 Annual Report on Form 10-K and Note 5 to the Company’s condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

In March 2010, the Company filed a registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings up to $100,000,000 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 registration statement became effective on April 13, 2010 (333-165677). The Company used this registration statement for its August 2010 and July 2011 public offerings detailed in Note 3 to the Company’s audited financial statements contained in the 2011 Annual Report on Form 10-K and for establishing an "at the market" equity offering program detailed in Note 5 to the Company’s condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q. As of March 31, 2012, Delcath had approximately $34.8 million available under its “at the market” equity offering program. The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of its products, funding of clinical trials, capital expenditures and working capital.

In December 2011, the Company filed an additional registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 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 registration statement became effective on February 13, 2012 (333-178819).

Critical Accounting Estimates

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted 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 1 to the Company’s financial statements contained in the 2011 Annual Report on Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the Delcath chemosaturation system as well as its research and development activities, the cost of which is required to be charged to expense as incurred. This further limits the Company’s choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company’s financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying FASB 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 FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB 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.

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The Company has adopted the provisions of FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

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

FASB 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, FASB 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 4 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 FASB ASC 820.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the value of its investments. However, the Company's marketable securities consist of short-term and/or variable rate instruments and, therefore, a change in interest rates would not have a material impact on the fair value of the Company's investment portfolio or related income.

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 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross 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 warrant liability. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's March 19, 2012 sale of common stock under the "at the market" equity offering

program as discussed in more detail in Note 5 of this filing. As of March 31, 2012, the 2009 Warrants were exercisable at $3.03 per share with 1,043,478 shares outstanding. The 2009 Warrants have a five-year term.

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In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and will expire on September 21, 2012. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock and were further adjusted following the Company's March 19, 2012 sale of common stock under the "at the market" equity offering program as discussed in more detail in Note 5 of this filing. At March 31, 2012, the 2007 Warrants were exercisable at $3.03 per share with 1,668,298 warrants outstanding. The shares were issued pursuant to an effective registration statement on Form S-3.

The $2.2 million in proceeds allocated to the 2009 Warrants and the $4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2012, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument expense of $0.3 million. The resulting derivative instrument liabilities totaled $2.9 million at March 31, 2012. The fair value of the Warrants at March 31, 2012 was determined by using an option pricing model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.14% for the 2007 Warrants, volatility of 82.83% for the 2009 Warrants and 90.74% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that Delcath's disclosure controls and procedures as of March 31, 2012 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There was no change in our internal control over financials reporting that occurred during the quarter ended March 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II:
OTHER INFORMATION

Item 1. Legal Proceedings

None.

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Item 1A. Risk Factors

Delcath's 2011 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 5. Other Information

Not Applicable.

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Item 6. Exhibits

Exhibit No.		Description
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	***	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	***	Certification of Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		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.

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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.

May 9, 2012

DELCATH SYSTEMS, INC.
(Registrant)

/s/Graham G. Miao
Graham G. Miao
Chief Financial Officer
(Principal Financial Officer)

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