DELCATH SYSTEMS INC
Form 10-Q
April 24, 2009

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, 2009.

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.)

600 Fifth Avenue, 23rd Floor, New York, NY 10020
(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 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 April 22, 2009, 25,355,254 shares of the Company's common stock, $0.01 par value, were issued and outstanding.

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(A Development Stage Company)

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PART I:
FINANCIAL INFORMATION

ItemCondensed Financial Statements (Unaudited)
1.

Index to Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Condensed Balance Sheets

	March 31, 2009 (Unaudited)	December 31, 2008 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$ 4,804,142	$ 6,939,233
Investments - CDs	3,893,356	3,847,904
Investments – treasury bills	–	200,710
Investments – marketable equity securities	19,000	22,000
Prepaid expenses	354,449	331,346
Total current assets	9,070,947	11,341,193
Property and equipment, net	16,024	17,489
Total assets	$ 9,086,971	$ 11,358,682
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 213,143	$ 703,489
Derivative instrument liability	1,010,096	448,318
Total current liabilities	1,223,239	1,151,807
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	–	–
Common stock, $.01 par value; 70,000,000 shares authorized	253,553	253,553
Additional paid-in capital	57,398,023	57,292,685
Deficit accumulated during development stage	(49,760,644)	(47,315,163)
Accumulated other comprehensive loss	(27,200)	(24,200)
Total stockholders' equity	7,863,732	10,206,875
Total liabilities and stockholders' equity	$ 9,086,971	$ 11,358,682

See accompanying notes to condensed financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,		Cumulative from Inception (August 5, 1988) to March 31,
	2009	2008	2009
Costs and expenses:			
General and administrative expenses	$ 474,964	$ 441,004	$ 23,254,063
Research and development costs	1,461,189	988,956	30,858,605
Total costs and expenses	$ 1,936,153	$ 1,429,960	$ 54,112,668
Operating loss	(1,936,153)	(1,429,960)	$ (54,112,668)
Derivative instrument (expense) income	(561,778)	198,251	3,258,904
Interest income	50,761	173,963	2,790,954
Other income	1,689	–	(74,311)
Interest expense	–	–	(171,473)
Net loss	$ (2,445,481)	$ (1,057,746)	$ (48,308,594)
Common share data:			
Basic and diluted loss per share	$ (0.10)	$ (0.04)	
Weighted average number of shares of common stock outstanding	25,355,254	25,259,284	

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Condensed Statement of Changes in Stockholders' Equity
(Unaudited)

	Common Stock $0.01 Par Value Issued and Outstanding						
	No. of Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage	Total	Other Comprehensive Loss
Balance at December 31, 2008	25,355,254	$ 253,553	$ 57,292,685	$ (24,200)	$ (47,315,163)	$ 10,206,875	–
Compensation expense for issuance of stock options	–	–	65,005	–	–	65,005	–
Compensation expense for issuance of stock	–	–	40,333	–	–	40,333	–
Components of comprehensive loss:	–	–	–	–	–		–
Change in unrealized loss on investments	–	–	–	(3,000)	–	(3,000)	$ (3,000)
Net loss	–	–	–	–	(2,445,481)	(2,445,481)	(2,445,481)
Total comprehensive loss	–	–	–	–	–	–	$ (2,448,481)
Balance at March 31, 2009	25,355,254	$ 253,553	$ 57,398,023	$ (27,200)	$ (49,760,644)	$ 7,863,732	

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,		Cumulative from inception (Aug. 5, 1988) to March 31,
	2009	2008	2009
Cash flows from operating activities:			
Net loss	$ (2,445,481)	$ (1,057,746)	$ (48,262,039)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	65,005	51,707	5,425,271
Stock and warrant compensation expense	40,333	–	1,184,611
Depreciation expense	1,465	1,466	53,227
Amortization of organization costs	–	–	42,165
Non-cash interest income	(45,452)	–	(53,356)
Derivative liability fair value adjustment	561,778	(198,251)	(3,258,904)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	(23,103)	(13,232)	(354,449)
Increase (decrease) in accounts payable and accrued expenses	(490,346)	(45,236)	213,143
Net cash used in operating activities	$ (2,335,801)	$ (1,261,292)	$ (45,010,331)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$ –	$ (8,313)	$ (69,252)
Purchase of short-term investments	–	(205,454)	(41,411,452)
Purchase of marketable equity securities	–	(46,200)	(46,200)
Proceeds from maturities of short-term investments	200,710	9,878,700	37,571,452
Organization costs	–	–	(42,165)
Net cash provided by (used in) investing activities	$ 200,710	$ 9,618,733	$ (3,997,617)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$ –	$ –	$ 52,657,764
Repurchases of common stock	–	–	(51,103)
Dividends paid on preferred stock	–	–	(499,535)
Proceeds from short-term borrowings	–	–	1,704,964
Net cash provided by financing activities	$ –	$ –	$ 53,812,090
Increase in cash and cash equivalents	(2,135,091)	8,357,441	4,804,142
Cash and cash equivalents at beginning of period	6,939,233	7,886,937	–
Cash and cash equivalents at end of period	$ 4,804,142	$ 16,244,378	$ 4,804,142
Supplemental cash flow information:			
Cash paid for interest	–	–	$ 171,473
Supplemental non-cash activities:			
Cashless exercise of stock options	$ –	$ –	$ 544,116
Conversion of debt to common stock	–	–	$ 1,704,964
Common stock issued for preferred stock dividends	–	–	$ 999,070
Conversion of preferred stock to common stock	–	–	$ 24,167

Common stock issued as compensation for stock sale	–	– $	510,000
Fair value of warrants issued	–	– $	4,269,000

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
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Notes to Condensed Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. (the "Company") is a development stage company that develops and manufactures an innovative device designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. The Company was incorporated in the State of Delaware in 1988 and since its inception has focused its efforts on the development of a single product, the Delcath PHP System™, for the treatment of tumors of the liver.

In 2006, the Company began a Phase III clinical trial to support a pre-market approval application for use of the Delcath PHP System™ with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is ongoing, and the Company hopes to complete enrollment of the trial in 2009. In 2004, the Company began a multi-arm Phase II clinical trial for use of the Delcath PHP System™ with certain other cancers that have spread to the liver and metastatic melanomas that have spread to the liver and have received certain prior regional treatment. The Company is focusing on enrolling patients in the neuroendocrine arm of that study. The other two arms treating metastatic adenocarcinomas and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the United States Food and Drug Administration (the "FDA") concerning a clinical trial that will focus on the effectiveness of the Delcath PHP System™ in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September 2008, the Company received approval from the FDA to begin working on that trial. To date, the Delcath PHP System™ has not been approved by the FDA.

Note 2: Basis of Financial Statement Presentation

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended March 31, 2009 and 2008, and cumulative from inception (August 5, 1988) to March 31, 2009.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2008, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2009 (the "2008 Form 10-K").

Certain reclassifications have been made to the 2008 financial statement presentation in order to correspond to the presentation of the March 31, 2009 financial statements.

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Note 3: Recently Adopted Accounting Pronouncements

In January 2009, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 161, "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"), which changes the disclosure requirements for derivative instruments and hedging activities. SFAS 161 requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133, "Accounting for Derivative Instruments and Hedging Activities" and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The adoption of SFAS 161 did not have a material impact on the condensed financial statements.

NoteCosts and Expenses
4:

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 our executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Note 5: Investment in Marketable Equity Securities

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc., ("AEMD") a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of this agreement, the Company received 100,000 shares of restricted common stock of AEMD. The Company allocated $46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement and then discounting that value due to certain sale restrictions on the stock being held. In September 2008, the sale restriction on the stock being held had lapsed and as a result the fair value of the stock is no longer being discounted. The investment is classified as an available for sale security and had a fair value on March 31, 2009 of $19,000 which included a gross unrealized loss of $27,200, which is included as a component of comprehensive loss.

NoteStockholders' Equity
6:

In January 2009, the Company granted 50,000 options to its President and Chief Executive Officer pursuant to the terms of his employment agreement. The per share weighted average fair value of the five-year stock option grant was $0.56 with a grant date exercise price equal to the common stock value at the date of grant, estimated on the date of grant using the Black-Scholes option-pricing model. All of these options vested immediately. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS No. 123R, "Share-Based Payment". The weighted-average

assumption of a risk free interest rate of 1.01% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 74.83% was

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estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The Company recognized compensation expense totaling $28,076 upon grant of these fully vested options.

The Company also recognized compensation expense of $36,929 in the first quarter of 2009 relating to options granted in previous years.

In July 2008, in accordance with an agreement with the new Chief Medical Officer, the Company granted 200,000 restricted shares of common stock which vest incrementally over three years that had an issuance value of $2.42. The Company has recognized compensation expense of $40,333 in the first quarter of 2009 relating to these shares.

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 in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to warrants (see below). The warrants are exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280).

The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with the Emerging Issues Task Force ("EITF") 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances, including its inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature. Accordingly, the warrants have been accounted for as derivative instrument liabilities that are subject to mark-to-market adjustment in each period. As a result, for the three month period ended March 31, 2009, the Company recorded pre-tax derivative instrument expense of $561,778. The resulting derivative instrument liability totaled $1,010,096 at March 31, 2009. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 1.28%, volatility of 71.04% and an expected life equal to the September 24, 2012 contractual life of the warrants.

NoteStock Option Plans
7:

The Company established the 2000 Stock Option Plan, the 2001 Stock Option Plan and the 2004 Stock Incentive Plan (collectively, the "Plans") under which 300,000, 750,000 and 3,000,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, and stock grants. 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 terms and conditions of each award, the option price and the duration of each award.

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During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and the 2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for the three-month period ended March 31, 2009 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2008	1,460,000	$1.23 – $6.18	$3.44	3.68
Granted	50,000	1.24	1.24	
Expired	-	-	-	
Exercised	-	-	-	
Outstanding at March 31, 2009	1,510,000	$1.23 – $6.18	$3.36	3.47

NoteAssets and Liabilities Measured at Fair Value
8:

Derivative financial instruments

Currently, the Company has allocated proceeds of warrants issued in connection with a private placement that were classified as a liability and accounted for as a derivative instrument in accordance with EITF 00-19, “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s own Stock.” The valuation of the warrants is determined using the Black-Scholes 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 inputs associated with fair value determination are readily observable and as a result the instrument is classified within Level 2 of the fair-value hierarchy.

Marketable Equity Securities

The Company owns 100,000 shares of common stock of AEMD. At March 31, 2009, the valuation of such stock is determined utilizing the current quoted market price of AEMD. The Company has determined that the inputs associated with the fair value determination are readily observable and as a result the instrument was classified within Level 1 of the fair-value hierarchy.

Money Market Funds and Certificates of Deposit

Cash and cash equivalents includes a money market account valued at $4,674,539.

The company also holds certificates of deposit valued at $3,893,356, which are classified as held to maturity. As such, the certificates of deposit are carried at amortized cost. The balance reflects a cost basis of $3,840,000 and $53,356 in accrued interest income.

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The Company has determined that the inputs associated with the fair value determination are based on quoted prices (unadjusted) and as a result the investments are 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 March 31, 2009, 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 at March 31, 2009

	Level 1	Level 2	Level 3	Balance at March 31, 2009
Assets				
Marketable equity securities	$ 19,000	$ —	$ —	$ 19,000
Money market funds	4,674,539	—	—	4,674,539
Certificates of deposit	3,893,356	—	—	3,893,356
Liabilities				
Derivative financial instruments	$ —	$ 1,010,096	$ —	$ 1,010,096

The Company does not have any fair value measurements using significant unobservable inputs (Level 3) as of March 31, 2009.

NoteIncome Taxes
9:

The Company adopted the provisions of the Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" ("FIN No. 48"), on January 1, 2007. FIN No. 48 requires that the impact of tax positions be recognized in the financial statements if they are more likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the financial statements in the 2008 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 their balance sheet under the provisions of FIN No. 48.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service ("the IRS") or any states in connection with income taxes. The periods from December 31, 2005 to December 31, 2008 remain open to examination by the IRS and state authorities.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed and consolidated financial statements and notes thereto contained in Item 1 of Part I of this Form 10-Q and our audited "financial statements and notes thereto as of and for the year ended December 31, 2008" included in our Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission to provide an understanding of our results of operations, financial condition and cash flows.

FORWARD-LOOKING STATEMENTS

This Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2008. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Form 10-Q other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "be "project," "expect," "anticipate" and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

These forward-looking statements speak only as of the date of this Form 10-Q. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.

Overview

We are a medical technology company that develops and manufactures an innovative device designed to administer high dose chemotherapy and other therapeutic agents directly to diseased organs or regions of the body. We are currently focusing on the development of a single product, the Delcath PHP System™, for the treatment of tumors of the liver. Based on human clinical data, we believe that the Delcath PHP System™ allows physicians to deliver significantly higher chemotherapy doses to the liver than could be administered by conventional intravenous delivery.

The Delcath PHP System™ is a disposable kit consisting of various catheters, filters, and a tubing circuit used during cancer treatment to isolate the liver from the patient's general circulatory system. Our system allows for ultra-high doses of chemotherapy agents to be directed at a patient's liver while at the same time limiting the exposure of healthy tissue and organs to the harmful effects of those chemotherapeutic agents. By providing higher dosing of chemotherapy agents than would otherwise be possible through conventional chemotherapy, we believe that treatment with the Delcath PHP System™ is more effective than conventional treatment at killing cancer cells and preventing new cancer cell formation.

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In 2006, we began a Phase III clinical trial to support a pre-market approval application for use of the Delcath PHP System™ with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is being conducted under the FDA's Special Protocol Assessment ("SPA"). Patients enrolled in this study currently receive treatment at the National Cancer Institute, or NCI, which serves as the coordinating center for this multi-center trial or at one of the other participating centers. The trial is currently approved for expansion to a maximum of 28 centers. In April 2008, the Institutional Review Board of the University of Maryland Medical Center agreed to participate in our Phase III study. In June 2008, St. Luke's Cancer Center, the Albany Medical Center, the Atlantic Melanoma Center of Atlantic Health and the University of Texas Medical Branch joined this clinical trial. In the third quarter, Swedish Medical Center of Colorado, John Wayne Cancer Institute, Providence Health Systems, and Moffitt Cancer Center agreed to join the clinical trial. In the fourth quarter of 2008, University of Pittsburgh Medical Center agreed to join the trial. Ohio State University Comprehensive Cancer Center recently joined the trial bringing the total to twelve centers. Each of the center's Institutional Review Board ("IRB") has approved our treatment protocol. Critical to expediting completion of this trial, the Western International Review Board, or WIRB, has also approved our protocol. The WIRB, which provides review services for more than 100 institutions (academic centers, hospitals, networks and in-house biotech research) in all 50 states and internationally, will help accelerate the internal review process at a number of the hospitals currently participating in the study. As of March 31, 2009, we have enrolled a total of 58 patients of the expected 92-patient trial. We expect to complete patient enrollment in this study in 2009. Once the FDA grants approval, we plan to conduct additional pre-clinical and clinical trials on the use of the Delcath PHP System™ with other chemotherapy agents used to treat cancer in the liver and seek additional FDA pre-market approvals.

In 2004, we began a multi-arm Phase II clinical trial for the use of the Delcath PHP System™ with melphalan in the treatment of hepatocellular carcinomas as well as neuroendocrine and adenocarcinoma cancers that have spread to the liver. In 2007, an additional arm was added to the Phase II trial to treat patients with metastatic melanomas that have spread to the liver who have received prior surgical isolated hepatic perfusion. Based on promising initial clinical results, we plan to focus our efforts on enrolling patients for the treatment of metastatic neuroendocrine cancer. We have currently enrolled 23 of the 25 patients required for the neuroendocrine arm of the trial and we anticipate that we will complete patient enrollment in this arm of the study in 2009.

As indicated above, the Company is focusing on enrolling patients in the neuroendocrine arm of the Phase II study. The other two arms treating adenocarcinoma and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the FDA concerning a clinical trial that will focus on the effectiveness of the Delcath PHP System™ in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September 2008, the Company received approval from the FDA to begin working on that trial.

The successful development of the Delcath PHP System™ is highly uncertain, and development costs and timelines can vary significantly and are difficult to accurately predict. Various statutes and regulations also impact the manufacturing, safety, labeling, storage, record keeping and marketing of our system. The lengthy process of completing clinical trials, seeking FDA approval and subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To

date, we have not received approval for the sale of our system in any market and, therefore, have not generated any revenues. The Delcath PHP System™ has not yet been approved by the FDA and may not be marketed in the United States without FDA pre-market approval.

In June 2008 and July 2008 we hired two senior executives. We hired a Chief Medical Officer to oversee the expansion of clinical activity, moving us towards the conclusion of our first Phase III clinical trial. We also hired a Senior Vice President for Regulatory Affairs and Quality Systems, a position newly created to manage the extensive FDA process. Our expenses generally include costs for clinical studies, securing patents, regulatory activities, manufacturing, personnel, rent for our facilities, and general corporate and working capital, including general and administrative expenses. Because we have no FDA-approved product and no commercial sales, we will continue to be dependent upon existing cash, the sale of equity or debt securities, or establishing a strategic alliance with appropriate partners to fund future activities. We cannot be assured that the pace of patient enrollment will meet our projections, that we will obtain FDA approval for our Delcath PHP System™, that we will have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for any of our products.

The Company's expenditures are highly variable and are dependent upon the number and pace of patients enrolled in our clinical trials. We expect that the amount of capital required for our trials will increase over the coming months due to the increased number of patients enrolled at newly added clinical trial centers. We believe that we have sufficient capital for operations through 2009 and to substantially advance our ongoing Phase III trial.

We are a development stage company, and since our inception we have raised approximately $52.7 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses over the coming years.

Results of Operations for the Three Months Ended March 31, 2009

We have operated at a loss for our entire history. We had a net loss for the three months ended March 31, 2009, of $2,445,481, which is a $1,387,735 increase in the net loss for the same period in 2008. The increase in net loss in 2009 is mainly attributable to a $760,029 fluctuation of derivative instrument income/expense, as well as to increased research and development costs related to the Phase III clinical trial.

General and administrative expenses increased from $441,004 during the three months ended March 31, 2008 to $474,964 for the three months ended March 31, 2009, or $33,960, a 7.7% change. This increase is primarily due to the addition of two members to the Board of Directors and an increase in fees paid to outside consultants.

During the three months ended March 31, 2009, we incurred $1,461,189 in research and development costs, as compared to $988,956 during the first quarter of 2008, an increase of $472,233. This increase is attributed to the continued expansion and acceleration of our Phase III clinical trial. During the first quarter of 2008 we had one center (the NCI) performing PHP™ treatments. For the same period of 2009, nine of our centers performed PHP™ treatments. The continued expansion of our Phase III trial has

created additional expenses related to patient treatment costs, clinical trial set-up expenses, IRB approvals, and other clinical expenses.

Interest income shown is from our money market account and investment in various certificates of deposit. During the three months ended March 31, 2009, the Company had interest income of $50,761, as compared to interest income of $173,963 for the same period in 2008. This decrease is due to our reduced cash position as we continue to direct our funds towards the completion of our Phase III trial, as well as the overall market conditions which continue to yield a lower percentage of return on our investments than the same period last year.

Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we anticipate that losses will continue for the foreseeable future. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including our ongoing Phase II and Phase III clinical trials; the timing and costs of making various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements overseas; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments. We continue to move forward aggressively, most notably by adding new sites to our ongoing clinical trials and increasing our efforts to enroll additional patients in these trials. As we seek FDA approval and get our product to market we expect that our capital expenditures will increase significantly.

At March 31, 2009, we had cash and cash equivalents of $4,804,142, as compared to $6,939,233 at December 31, 2008. Nearly all of our available funds are invested in money market accounts and certificates of deposit.

During the three months ended March 31, 2009, we used $2,335,801 of cash in our operating activities. This amount compares to $1,261,292 used in our operating activities during the comparable three month period in 2008. The increase of $1,074,509, or 85.2%, is primarily due to increased payroll expenses related to the hiring of two senior executives in the second half of 2008 and accelerated clinical development costs related to all facets of the Delcath PHP System™. We expect that our cash allocated to operating activities will continually increase as we aggressively move toward the full enrollment and completion of our first Phase III clinical trial, and continue to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our current clinical trials through 2009. Even in light of potential increased expenditures, we believe that our cash and cash equivalents will be adequate to satisfy our capital needs through fiscal 2009.

At March 31, 2009, the Company's accumulated deficit was approximately $49.8 million. Because our business does not generate any positive cash flow from operating activities, we will likely need to raise additional capital to develop our product beyond the current clinical trials or to fund development efforts relating to new products. We anticipate that we could raise additional capital in the event that we find it in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the

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extent additional capital is not available when we need it, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from those planned because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003 along with our registered direct offering in 2007. Please see the detailed discussion of our various sales of securities described in Note 3 of the financial statements in the 2008 Form 10-K.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with 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 our financial statements contained in our 2008 Form 10-K. We are still in the development stage and have no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore have very limited opportunities to choose among accounting policies or methods. In many cases, we must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, we devote substantial resources to clinical trials and other research and development activities relating to obtaining FDA and other approvals for the Delcath PHP System™, the cost of which is required to be charged to expense as incurred. This further limits our choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which our financial statement estimates are significant or critical.

We consider the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying SFAS No. 109, “Accounting for Income Taxes,” management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that we will realize the benefits of our deferred tax assets. Management believes the Company does not have any uncertain tax positions as defined under FASB Interpretation No. 48 “Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109.”

The Company has adopted the provisions of SFAS 123R. SFAS 123R establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, 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). Effective January 1, 2006, the Company adopted the modified prospective approach and, accordingly, prior period amounts have not been restated. Under this approach, the Company is required to record compensation cost for all share-based payments granted after the date of adoption based upon the grant date fair value, estimated in accordance with the provisions of SFAS 123R, and for the unvested portion of all share-based payments previously granted that remain outstanding based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123. The Company has expensed its share-based compensation for share-based payments granted after January 1, 2006 under the ratable method, which treats each vesting tranche as if it were an individual grant.

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On January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS No. 157 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances. The adoption of SFAS No. 157 did not have a material effect on the carrying values of the Company's assets.

SFAS No. 157 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, SFAS No. 157 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.

ItemQuantitative and Qualitative Disclosures about Market Risk
3.

We may be exposed to market risk through changes in market interest rates that could affect the value of our 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 our investment portfolio or related income.

In January 2008, the Company entered into a research and development agreement with AEMD, a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of this agreement, the Company received 100,000 shares of restricted common stock of AEMD. The Company allocated $46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement and then discounting that value due to certain sale restrictions on the stock being held. During the quarter ending September 30, 2008, the restriction on the common stock held lapsed and as a result the fair value of the stock is calculated using the closing stock price (unadjusted) at March 31, 2009. The investment is classified as an available for sale security and had a fair value on March 31, 2009 of $19,000, which included a gross unrealized loss of $27,200, which is included as a component of comprehensive loss.

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The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them in the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract. In 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 in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to warrants. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280). The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances; including the Company's inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature in certain circumstances. Accordingly, the warrants have been accounted for as derivative instrument liabilities, which are subject to mark-to-market adjustment in each period. As a result, for the three month period ended March 31, 2009, the Company recorded derivative instrument expense of $561,778. The resulting derivative instrument liability totaled $1,010,096 at March 31, 2009. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 1.28%, volatility of 71.04% and an expected life equal to the September 24, 2012 contractual life of the warrants.

ItemControls and Procedures
4.

Based on an evaluation of the Company's disclosure controls and procedures performed by the Company's Principal Executive Officer and Principal Financial Officer as of the end of the period covered by this report, the Company's Principal Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures have been effective.

As used herein, "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms issued by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer or officers and its principal financial officer or officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation described above that occurred during the period covered by this report that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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PART II:
OTHER INFORMATION

ItemLegal Proceedings
1.

Not Applicable.

ItemRisk Factors
1A.

Our 2008 Form 10-K contains a detailed discussion of certain risk factors that could materially adversely affect our business, operating results or financial condition. There were no material changes in these risk factors since such disclosure.

ItemUnregistered Sales of Equity Securities and Use of Proceeds
2.

Not Applicable.

Item Defaults upon Senior Securities
3.

Not Applicable.

Item Submission of Matters to a Vote of Security Holders
4.

Not Applicable.

ItemOther Information
5.

Not Applicable.

ItemExhibits
6.

31.1 Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

31.2 Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

32.1 Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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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.

April 24, 2009

DELCATH SYSTEMS, INC.
(Registrant)

/s/ Barbra Keck
Barbra Keck
Controller
(Principal financial officer)

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(A Development Stage Company)

EXHIBIT INDEX

Exhibit No.	Description
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