

DELCATH SYSTEMS INC  
Form 10-Q  
July 28, 2009

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2009.

☐ 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	(I.R.S. Employer
jurisdiction of	Identification No.)
incorporation or	
organization)	

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

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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 ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of July 27, 2009, 26,316,485 shares of the Company’s common stock, \$0.01 par value were outstanding.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

PART I:

FINANCIAL INFORMATION

Item Condensed Financial Statements (Unaudited)

1.

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

	June 30, 2009 (Unaudited)	December 31, 2008 (Audited)
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 7,435,673	\$ 6,939,233
Investments - CDs	1,472,928	3,847,904
Investments – treasury bills	–	200,710
Investments – marketable equity securities	36,000	22,000
Income tax receivable	298,535	–
Prepaid expenses	324,253	331,346
Total current assets	9,567,389	11,341,193
Property and equipment, net	14,558	17,489
Total assets	\$ 9,581,947	\$ 11,358,682
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 344,083	\$ 703,489
Derivative instrument liability	7,105,454	448,318
Total current liabilities	7,449,537	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; 26,252,919 and 25,383,354 shares issued and 26,224,819 and 25,355,254 outstanding at June 30, 2009 and December 31, 2008, respectively	262,530	253,834
Additional paid-in capital	58,019,453	57,343,507
Deficit accumulated during development stage	(56,088,270)	(47,315,163)
Treasury stock at cost, 28,100 shares at June 30, 2009 and December 31, 2008	(51,103)	(51,103)
Accumulated other comprehensive loss	(10,200)	(24,200)
Total stockholders' equity	2,132,410	10,206,875
Total liabilities and stockholders' equity	\$ 9,581,947	\$ 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 June 30,		Six Months Ended June 30,		Cumulative from Inception (Aug 5, 1988) to June 30, 2009
	2009	2008	2009	2008	2009
<b>Costs and expenses:</b>					
General and administrative expenses	\$ 544,913	\$ 699,136	\$ 1,019,876	\$ 1,140,140	\$ 23,798,975
Research and development costs	2,195,036	1,099,488	3,656,226	2,088,444	33,053,642
Total costs and expenses	\$ 2,739,949	\$ 1,798,624	\$ 4,676,102	\$ 3,228,584	\$ 56,852,617
Operating loss	(2,739,949)	(1,798,624)	(4,676,102)	(3,228,584)	\$ (56,852,617)
Derivative instrument (expense) income	(3,904,379)	(671,652)	(4,466,157)	(473,401)	(645,475)
Interest income	18,167	50,002	68,928	223,965	2,855,676
Other income	—	—	1,689	—	(74,311)
Interest expense	—	—	—	—	(171,473)
Net loss before tax benefit	\$ (6,626,161)	\$ (2,420,274)	\$ (9,071,642)	\$ (3,478,020)	\$ (54,888,200)
Income tax benefit	298,535	—	298,535	—	298,535
Net loss	\$ (6,327,626)	\$ (2,420,274)	\$ (8,773,107)	\$ (3,478,020)	\$ (54,589,665)
<b>Common share data:</b>					
Basic and diluted loss per share	\$ (0.25)	\$ (0.10)	\$ (0.34)	\$ (0.14)	
<b>Weighted average number of shares of common stock outstanding</b>					
	25,528,282	25,262,031	25,455,818	25,260,658	

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		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage	Total	Other Comprehensive Loss
	No. of Shares	Amount	No. of Shares	Amount					
Balance at January 1, 2009	25,383,354	\$ 253,834	28,100	\$ (51,103)	\$ 57,343,507	\$ (24,200)	\$ (47,315,163)	\$ 10,206,875	
Compensation expense for issuance of stock options	—	—	—	—	120,555	—	—	120,555	
Compensation expense for issuance of stock	—	—	—	—	80,667	—	—	80,667	
Sale of stock (including 1,043,478 warrants to purchase one share of common stock at \$3.99)	869,565	8,696	—	—	474,724	—	—	483,420	
Components of comprehensive loss:	—	—	—	—	—	—	—	—	—
Change in unrealized loss on investments	—	—	—	—	—	14,000	—	14,000	\$ 14,000
Net loss	—	—	—	—	—	—	(8,773,107)	(8,773,107)	(8,773,107)
Total comprehensive loss	—	—	—	—	—	—	—	—	\$(8,759,107)
Balance at June 30, 2009	26,252,919	\$ 262,530	28,100	\$ (51,103)	\$ 58,019,453	\$ (10,200)	\$ (56,088,270)	\$ 2,132,410	



See accompanying notes to condensed financial statements.

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

	Six Months Ended June 30,		Cumulative from inception (Aug. 5, 1988) to June 30, 2009
	2009	2008	2009
<b>Cash flows from operating activities:</b>			
Net loss	\$ (8,773,107)	\$ (3,478,020)	\$ (54,589,665)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	120,555	70,586	5,480,821
Stock and warrant compensation expense	80,667	120,700	1,224,945
Depreciation expense	2,931	2,930	54,693
Amortization of organization costs	—	—	42,165
Non-cash interest income	(32,928)	—	(40,832)
Derivative liability fair value adjustment	4,466,157	473,401	645,475
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	7,093	34,903	(324,253)
Increase in income tax receivable	(298,535)	—	(298,535)
Increase (decrease) in accounts payable and accrued expenses	(359,406)	30,671	344,083
Net cash used in operating activities	\$ (4,786,573)	\$ (2,744,829)	\$ (47,461,103)
<b>Cash flows from investing activities:</b>			
Purchase of equipment or furniture and fixtures	\$ —	\$ (8,313)	\$ (69,252)
Purchase of short-term investments	—	(203,172)	(41,411,452)
Purchase of marketable equity securities	—	(46,200)	(46,200)
Proceeds from maturities of short-term investments	2,608,614	9,878,700	39,979,356
Organization costs	—	—	(42,165)
Net cash provided by (used in) investing activities	\$ 2,608,614	\$ 9,621,015	\$ (1,589,713)
<b>Cash flows from financing activities:</b>			
Net proceeds from sale of stock and exercise of stock options and warrants	\$ 2,674,399	\$ —	\$ 55,332,163
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	\$ 2,674,399	\$ —	\$ 56,486,489
Increase in cash and cash equivalents	496,440	6,876,186	7,435,673
Cash and cash equivalents at beginning of period	6,939,233	7,886,937	—
Cash and cash equivalents at end of period	\$ 7,435,673	\$ 14,763,123	\$ 7,435,673
<b>Supplemental cash flow information:</b>			
Cash paid for interest	—	—	\$ 171,473
<b>Supplemental non-cash activities:</b>			
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

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Conversion of preferred stock to common stock	–	– \$	24,167
Common stock issued as compensation for stock sale	–	– \$	510,000
Fair value of warrants issued	2,190,979	– \$	6,459,979

See accompanying notes to condensed financial statements.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

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 Percutaneous Hepatic Perfusion (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. In September 2008, the Company received approval from the FDA to begin 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.

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”) 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 interim 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 June 30, 2009 and 2008, and cumulative from inception (August 5, 1988) to June 30, 2009. In connection with the preparation of the condensed financial statements and in accordance with the recently issued Statement of Financial Accounting Standards (“SFAS”) No. 165 “Subsequent Events” (“SFAS 165”), the Company evaluated subsequent events after the balance sheet date of June 30, 2009 through July 23, 2009.

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 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 June 30, 2009 financial statements.



DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Note 3: Recently Adopted Accounting Pronouncements

In January 2009, the Company adopted SFAS 161, "Disclosures about Derivative Instruments and Hedging Activities," 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.

Note 4:  
Costs and Expenses

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 June 30, 2009 of \$36,000 which included a gross unrealized loss of \$10,200, which is included as a component of comprehensive loss.

Note 6:  
Stockholders' Equity

In June 2009, the Company granted an employee 10,000 options with a grant date exercise price equal to the common stock value at the date of grant. The per share weighted average fair value of the five-year stock option grant was \$1.86, 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

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accordance with SFAS 123R, "Share-Based Payment." The weighted-average assumption of a risk free interest rate of 1.63% 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 85.05% was estimated based upon the historical volatility of the Company's share price over the length of time equal to the expected term of the options. 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 foreseeable future. The Company recognized compensation expense totaling \$18,622 upon grant of these fully vested options.

In January 2009, the Company granted 50,000 options to its former President and Chief Executive Officer pursuant to the terms of his employment agreement. The options have a grant date exercise price equal to the common stock value at the date of grant. The per share weighted average fair value of the five-year stock option grant was \$0.56, 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 123R. 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 estimated based upon the historical volatility of the Company's share price over the length of time equal to the expected term of the options. 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 foreseeable future. The Company recognized compensation expense totaling \$28,076 upon grant of these fully vested options.

For the three months ended June 30, 2009, the Company recognized compensation expense of \$36,929 relating to options granted in previous years. For the six months ended June 30, 2009, the Company recognized compensation expense of \$73,857 relating to options granted in previous years.

In July 2008, the Company granted 200,000 restricted shares of common stock in accordance with an agreement with our Chief Medical Officer. These shares had an issuance value of \$2.42 per share and vest incrementally over three years. The Company has recognized compensation expense totaling \$80,667 for 2009, \$40,333 in each quarter, relating to these shares.

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 \$2,999,999 and estimates the net cash proceeds after related expenses from this transaction will be \$2,674,399. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants (see below), resulting in estimated net proceeds of \$483,420. The fair value of the 2009 Warrants on June 15, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the warrants (June 2014). The 2009 Warrants are exercisable at \$3.99 per share and have a five-year term. The shares and warrants were offered pursuant to an effective registration statement on Form S-3 filed with the SEC on May 25, 2007 (333-143280), effective June 7, 2007, as amended by a registration statement on Form S-3 filed with the SEC and effective on June 10, 2009 (333-159857).

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 \$13,303,267



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in this transaction. The Company allocated \$4,269,000 of the total proceeds to 2007 Warrants (see below). The 2007 Warrants were initially 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. 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. The 2007 Warrants are currently exercisable at \$3.44 per share with 2,523,834 warrants outstanding. The shares were offered pursuant to the registration statement on Form S-3 filed with the SEC on May 25, 2007 and declared effective on June 7, 2007 (333-143280).

The \$2,190,979 in proceeds allocated to the 2009 Warrants and the \$4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities in accordance with SFAS 133 and related interpretations. 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 six month period ended June 30, 2009, the Company recorded pre-tax derivative instrument expense of \$4,466,157. The resulting derivative instrument liability totaled \$7,105,454 at June 30, 2009. Management expects that the Warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to stockholders' equity. The fair value of the Warrants at June 30, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.54% for the 2009 Warrants and 1.75% for the 2007 Warrants, volatility of 73.12% for the 2009 Warrants and 78.25% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

NoteStock Option Plans

7:

The Company established the 2000 Stock Option Plan, the 2001 Stock Option Plan, the 2004 Stock Incentive Plan, and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 300,000, 750,000, 3,000,000, and 2,000,000 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 2000, 2001, 2004 and 2009, respectively, the 2000 and 2001 Stock Option Plans and 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 six-month period ended June 30, 2009 is as follows:

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		The Plans		
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
		1.23 –		
Outstanding at December 31, 2008	1,460,000	\$ 6.18	\$ 3.44	3.68
Granted	60,000	1.24 – 3.66	1.64	-
Expired	-	-	-	-
Exercised	-	-	-	-
		1.23 –		
Outstanding at June 30, 2009	1,520,000	\$ 6.18	\$ 3.37	3.25

Note Assets and Liabilities Measured at Fair Value  
8:

#### Derivative financial instruments

Currently, the Company has allocated part of the proceeds of a private placement and of a registered direct offering to the Warrants issued in connection with both common stock sales. The Warrants are classified as a liability and accounted for as a derivative instrument in accordance with SFAS 133. 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 the expected life of the instrument. The Company has determined that the inputs associated with the 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 June 30, 2009, the valuation of such stock was determined utilizing the current quoted market price of AEMD. The Company has determined that the quoted market price is readily observable in an active market 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 \$7,340,823.

The Company also holds certificates of deposit valued at \$1,472,928, 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 \$1,440,000 and \$32,928 in accrued interest income. The Company has determined that the quoted price (unadjusted) is readily observable in an active market 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 June 30, 2009, aggregated by the level in the fair value hierarchy within which those measurements fall:

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DELCATH SYSTEMS, INC.  
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## Assets and Liabilities Measured at Fair Value on a Recurring Basis at June 30, 2009

	Level 1	Level 2	Level 3	Balance at June 30, 2009
<b>Assets</b>				
Marketable equity securities	\$ 36,000	\$ –	\$ –	\$ 36,000
Money market funds	7,340,823	–	–	7,340,823
Certificates of deposit	1,472,928	–	–	1,472,928
<b>Total Assets</b>	<b>\$ 8,849,751</b>	<b>\$ –</b>	<b>\$ –</b>	<b>\$ 8,849,751</b>
<b>Liabilities</b>				
Derivative financial instruments	\$ –	\$ 7,105,454	\$ –	\$ 7,105,454
<b>Total Liabilities</b>	<b>\$ –</b>	<b>\$ 7,105,454</b>	<b>\$ –</b>	<b>\$ 7,105,454</b>

The Company does not have any fair value measurements using significant unobservable inputs (Level 3) as of June 30, 2009.

## Note 9: Income 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 48”), on January 1, 2007. FIN 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 Note 4 to the Company’s audited financial statements contained 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 its balance sheet under the provisions of FIN 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.

For the quarter ending June 30, 2009, the Company recorded a state income tax benefit of \$298,535 in the Statement of Operations. This benefit is a result 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. Of the total benefit, \$173,535 relates to 2008 research and development expense credits and \$125,000 relates to the estimated 2009 quarter to date benefit.

## Note 10: Subsequent Events

Effective July 6, 2009, Mr. Eamonn Hobbs was appointed President and Chief Executive Officer of the Company. Mr. Hobbs replaces Mr. Richard Taney, who will continue as a member of the Board of Directors of the Company.

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DELCATH SYSTEMS, INC.  
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As of June 30, 2009, we had enrolled a total of 72 patients of the expected 92-patient Phase III clinical trial. Between July 1, 2009 and July 27, 2009 we have enrolled an additional 7 patients, bringing total enrollment to 79 patients.

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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 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 an FDA Special Protocol Assessment (“SPA”) with the National Cancer Institute (the “NCI”) serving as the coordinating center. The trial is currently approved for expansion to a maximum of 28 centers. Until April 2008, the NCI was the sole participating center in the trial. Since then, eleven centers have joined the trial, bringing the total number of participating centers to twelve:

2008,  
2nd Quarter

University of  
Maryland  
Medical Center  
St. Luke’s Cancer  
Center

Albany Medical  
Center

Atlantic  
Melanoma  
Center of  
Atlantic Health  
University of  
Texas Medical  
Branch

2008, 3rd Quarter

Swedish Medical  
Center

John Wayne  
Cancer Institute  
Providence  
Health Systems  
Moffitt Cancer  
Center

2008, 4th Quarter

University of  
Pittsburgh  
Medical Center

2009, 1st Quarter

Ohio State  
University  
Comprehensive  
Cancer Center



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Each participating center's Institutional Review Board ("IRB") has approved our treatment protocol. Critical to expediting completion of this trial, the Western Institutional Review Board ("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 June 30, 2009, we had enrolled a total of 72 patients of the expected 92-patient trial. Between July 1, 2009 and July 27, 2009 we have enrolled an additional 7 patients, bringing total enrollment to 79 patients. We expect to complete patient enrollment in this study in 2009. 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. In September 2008, the Company received approval from the FDA to begin 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.

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.

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 our product.

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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 continue to 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 complete enrollment of our ongoing Phase III trial.

We are a development stage company, and since our inception we have raised approximately \$55.3 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 year.

As previously reported in our Current Report on Form 8-K filed with the SEC on July 7, 2009, effective July 6, 2009, Eamonn Hobbs was appointed President and Chief Executive Officer of the Company. Mr. Hobbs has been a director of the Company since October 2008. He has over 25 years of experience in the interventional radiology, interventional cardiology and gastroenterology medical device industries. Mr. Hobbs replaces Richard Taney, who resigned effective July 6, 2009, as President and Chief Executive Officer of the Company. Mr. Taney will continue as a member of the Board of Directors of the Company.

#### Results of Operations

##### Three Months Ended June 30, 2009 and June 30, 2008

We have operated at a loss for our entire history. We had a net loss for the three months ended June 30, 2009, of \$6,327,626, which is a \$3,907,352 increase in the net loss for the same period in 2008. The increase in net loss in 2009 is due to a \$3,232,727 increase in derivative instrument expense related to the Warrants, as well as an increase of \$1,095,548 in research and development costs related to the Phase III clinical trial.

General and administrative expenses decreased by 22.1%, from \$699,136 during the three months ended June 30, 2008 to \$544,913 for the three months ended June 30, 2009, a reduction of \$154,223. This decrease is primarily due to a reduction in fees paid to outside consultants.

For the three months ended June 30, 2009, research and development expenses increased by 100%, from \$1,099,488 during the second quarter of 2008 to \$2,195,036, an increase of \$1,095,548. This increase is attributed to the continued expansion and acceleration of our Phase III clinical trial. During the second quarter of 2008 we had one center (the NCI) performing PHP™ treatments. For the same period of 2009 we have twelve centers participating in our Phase III clinical trial. The continued expansion of our Phase III clinical trial has created additional expenses related to patient treatment costs, 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 June 30, 2009, the Company had interest income of \$18,167, as compared to \$50,002 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 clinical 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.



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Six Months Ended June 30, 2009 and June 30, 2008

We had a net loss of \$8,773,107 for the six months ended June 30, 2009. This compares to a net loss of \$3,478,020 for the same period of 2008. The increase of \$5,295,087 in net loss is related to a nearly \$3,992,756 increase in derivative instrument expense related to the Warrants, as well as a \$1,567,782 increase in research and development costs.

For the six months ended June 30, 2009, we incurred \$1,019,876 in expenses related to our general and administrative operations. This is a 10.5% decrease from the same period in 2008, when we incurred \$1,140,140 in general and administrative expenses. This decrease is primarily related to a reduction in fees paid to outside consultants.

For the six months ended June 30, 2009, research and development costs increased by 75.1%, from \$2,088,444 for the first six months of 2008 to \$3,656,226 for the six months ended June 30, 2009, a \$1,567,782 increase. This change is due to the increasing pace of enrollment in our Phase III clinical trial. As the Company gets closer to full enrollment of the trial we anticipate expenses related to the clinical trial and the Company's preparations for FDA submission to continue their acceleration.

Interest income shown is from our money market account and investment in various certificates of deposit. During the six months ended June 30, 2009, the Company had interest income of \$68,928, as compared to interest income of \$223,965 for the same period in 2008. As discussed above, 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 June 30, 2009, we had cash and cash equivalents of \$7,435,673, 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 six months ended June 30, 2009, we used \$4,786,573 of cash in our operating activities. This amount compares to \$2,744,829 used in our operating activities during the comparable six month period in 2008. The increase of \$2,041,744, or 74%, is primarily due to accelerated clinical development costs related to all facets of the Phase III clinical trials





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and 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.

At June 30, 2009, the Company's accumulated deficit was approximately \$56.1 million. Because our business does not generate any positive cash flow from operating activities, we will likely need to continue raising additional capital in order 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 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 offerings in 2007 and 2009. Please see the detailed discussion of our various sales of securities described in Note 3 to the Company's audited financial statements contained in the 2008 Form 10-K and in Note 6 to the Company's condensed financial statements contained in this Form 10-Q.

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 \$2,999,999 and estimates the net cash proceeds after related expenses from this transaction will be \$2,674,399. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants (see below), resulting in estimated net proceeds of \$483,420. The fair value of the 2009 Warrants on June 15, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the warrants (June 2014). The 2009 Warrants are exercisable at \$3.99 per share and have a five-year term. The shares and warrants were offered pursuant to an effective registration statement on Form S-3 filed with the SEC on May 25, 2007 (333-143280), effective June 7, 2007, as amended by a registration statement on Form S-3 filed with the SEC and effective on June 10, 2009 (333-159857).

In June 2009, the Company filed a registration statement on Form S-3 with the SEC, which will allow the Company to offer and sell, from time to time in one or more offerings up to \$60,000,000 of common stock, preferred stock, stock purchase contracts, warrants and debt securities as it deems prudent or necessary to raise capital at a later date. The registration statement became effective on June 23, 2009 (333-159913). The Company intends to use the net proceeds from any future offerings under the registration for general corporate purposes, including, but not limited to, funding our clinical trials, capital expenditures, working capital, repayment of debt and investments. Because the maximum aggregate offering price of all securities registered is \$60,000,000, the Company's issuance of any securities will reduce the amount of other securities that it can issue pursuant to the registration statement on Form S-3.



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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 the Company's financial statements contained in the 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 related 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 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 FIN 48.

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.

On January 1, 2008, the Company adopted SFAS 157, "Fair Value Measurements," which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 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 157 did not have a material effect on the carrying values of the Company's assets.

SFAS 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 157 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity



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(observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 8 to the Company's condensed financial statements contained in this Form 10-Q for assets and liabilities the Company has evaluated under SFAS 157.

Item Quantitative 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 restrictions 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 June 30, 2009. The investment is classified as an available for sale security and had a fair value on June 30, 2009 of \$36,000, which included a gross unrealized loss of \$10,200, which is included as a component of comprehensive loss.

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) in a subscription agreement with a single investor. The Company received gross proceeds of \$2,999,999 and estimates the net cash proceeds after related expenses from this transaction will be \$2,674,399. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants, resulting in estimated net proceeds of \$483,420. The fair value of the 2009 Warrants on June 15, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life



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equal to the contractual life of the 2009 Warrants (June 2014). The 2009 Warrants are exercisable at \$3.99 per share and have a five-year term.

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 \$13,303,267 in this transaction. The Company allocated \$4,269,000 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 on or prior to the fifth anniversary of the issuance thereof. 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. The 2007 Warrants are currently exercisable at \$3.44 per share with 2,523,834 warrants outstanding.

The \$2,190,979 in proceeds allocated to the 2009 Warrants and the \$4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities in accordance with SFAS 133 and related interpretations. The terms of the 2007 Warrants and the 2009 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 six month period ended June 30, 2009, the Company recorded pre-tax derivative instrument expense of \$4,466,157. The resulting derivative instrument liability totaled \$7,105,454 at June 30, 2009. Management expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to stockholders' equity. The fair value of the Warrants at June 30, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.54% for the 2009 Warrants and 1.75% for the 2007 Warrants, volatility of 73.12% for the 2009 Warrants and 78.25% 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

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 are 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 (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) 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.

ItemDefaults upon Senior Securities

3.

Not Applicable.

ItemSubmission of Matters to a Vote of Security Holders

4.

On June 9, 2009, the Company held its Annual Meeting of Stockholders, at which the following matters were voted upon:

Election of Directors - The following individuals were re-elected to the Board of Directors for a three year term by the following vote:

Name	For	Withheld
Laura A. Philips	19,736,287	956,717
Roger G. Stoll	20,533,365	139,639

The following are the individuals whose term of office as a director continued after the meeting:

Name

Pamela R. Contag

Eamonn Hobbs

Harold S. Koplewicz

Robert B. Ladd

Richard L. Taney

Selection of Auditors - The selection by the Company's Audit Committee of CCR LLP as independent auditors of the Company for the fiscal year ending December 31, 2009 was ratified by the following vote: 20,609,354 For; 44,114 Against; 39,537 Abstentions; 0 Broker Non-Votes.

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Approval of the Company's 2009 Stock Incentive Plan (the "Plan") – The Plan proposed by management was approved by the following vote: 6,875,385 For; 1,482,977 Against; 227,785 Abstentions; 0 Broker Non-Votes.

ItemOther Information

5.

Not Applicable.

ItemExhibits

6.

4.1 Form of Warrant to Purchase Shares of Common Stock issued pursuant to the Subscription Agreement dated June 9, 2009 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 10, 2009).

10.1 2009 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's proxy statement on Schedule 14A filed April 30, 2009).

10.2 Placement Agency Agreement, dated June 9, 2009 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed June 10, 2009).

10.3 Subscription Agreement, dated June 9, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 10, 2009).

10.4 Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 10, 2009).

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.

July 28, 2009

DELCATH SYSTEMS, INC.  
(Registrant)

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

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EXHIBIT INDEX

Exhibit No.	Description
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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