DELCATH SYSTEMS INC
Form 10-Q
October 23, 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 September 30, 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 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 o 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 October 23, 2009, 26,316,485 shares of the Company's common stock, $0.01 par value were outstanding.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

DELCATH SYSTEMS, INC.

Index

DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:

FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Index to Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Balance Sheets

	September 30, 2009 (Unaudited)	December 31, 2008 (Audited)
Assets:		
Current assets		
Cash and cash equivalents	$6,038,590	$6,939,233
Investments – CDs	–	3,847,904
Investments – treasury bills	–	200,710
Investments – marketable equity securities	28,000	22,000
Income tax receivable	361,035	–
Prepaid expenses	305,092	331,346
Total current assets	6,732,717	11,341,193
Property and equipment, net	33,386	17,489
Total assets	$6,766,103	$11,358,682
Liabilities and Stockholders' (Deficit) Equity:		
Current liabilities		
Accounts payable and accrued expenses	$772,111	$703,489
Derivative instrument liability	10,936,255	448,318
Total current liabilities	11,708,366	1,151,807
Commitments and contingencies	–	–
Stockholders' (deficit) 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; 26,344,585 and 25,383,354 shares issued and 26,316,485and 25,355,254 outstanding at September 30, 2009 and December 31, 2008, respectively	263,446	253,834
Additional paid-in capital	58,537,767	57,343,507
Deficit accumulated during development stage	(63,674,173)	(47,315,163)
Treasury stock, at cost; 28,100 shares at September 30, 2009 and December 31, 2008	(51,103)	(51,103)
Accumulated other comprehensive loss	(18,200)	(24,200)
Total stockholders' (deficit) equity	(4,942,263)	10,206,875
Total liabilities and stockholders' (deficit) equity	$6,766,103	$11,358,682

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative from Inception (Aug 5, 1988) to September 30,
	2009	2008	2009	2008	2009
Costs and expenses:					
General and administrative expenses	$1,493,490	$589,900	$2,513,366	$1,730,040	$25,292,465
Research and development costs	2,327,167	1,624,379	5,983,392	3,712,823	35,380,809
Total costs and expenses	$3,820,657	$2,214,279	$8,496,758	$5,442,863	$60,673,274
Operating loss	(3,820,657)	(2,214,279)	(8,496,758)	(5,442,863)	(60,673,274)
Derivative instrument (expense) income	(3,830,801)	1,280,748	(8,296,958)	807,347	(4,476,276)
Interest income	3,054	55,674	71,982	279,639	2,858,730
Other income	–	–	1,689	–	(74,311)
Interest expense	–	–	–	–	(171,473)
Net loss before tax benefit	$(7,648,404)	$(877,857)	$(16,720,045)	$(4,355,877)	$(62,536,604)
Income tax benefit	62,500	–	361,035	–	361,035
Net loss	$(7,585,904)	$(877,857)	$(16,359,010)	$(4,355,877)	$(62,175,569)
Common share data:					
Basic and diluted loss per share	$(0.29)	$(0.03)	$(0.64)	$(0.17)	
Weighted average number of shares of common stock outstanding	26,337,717	25,334,244	25,753,795	25,285,366	

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statement of Changes in Stockholders' (Deficit) Equity

(Unaudited)

	Common Stock $0.01 Par Value Issued and Outstanding		Treasury Stock		Additional Paid	Deficit Accumulated During Development		Other Comprehensive
	No. of Shares	Amount	No. of Shares	Amount	in Capital	Stage	Total	Loss
Balance at January 1, 2009	25,383,354	$253,834	28,100	$(51,103)	$57,343,507	$(47,315,163)	$10,206,875	
Compensation expense for issuance of stock options	-				502,534		502,534	
Compensation expense for issuance of stock	91,666	916			224,167		225,083	
Sale of stock (including 1,043,478 warrants to purchase one share of common stock at $3.99)	869,565	8,696			467,559		476,255	
Components of comprehensive loss:								
Change in unrealized loss on investments	-						6,000	$6,000
Net loss	-					(16,359,010)	(16,359,010)	(16,359,010)
Total comprehensive loss	-							$(16,353,010)
Balance at September 30, 2009	26,344,585	$263,446	28,100	$(51,103)	$58,537,767	$(63,674,173)	$(4,942,263)	

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,		Cumulative from inception (Aug. 5, 1988) to September 30,
	2009	2008	2009
Cash flows from operating activities:			
Net loss	$ (16,359,010)	$ (4,355,877)	$ (62,175,568)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	502,534	40,333	5,862,800
Stock and warrant compensation expense	225,083	333,511	1,369,361
Depreciation expense	5,027	4,395	56,789
Amortization of organization costs	–	–	42,165
Non-cash interest income	–	–	(7,904)
Derivative liability fair value adjustment	8,296,958	(807,347)	4,476,276
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	26,254	65,105	(305,092)
Increase in income tax receivable	(361,035)	–	(361,035)
Increase (decrease) in accounts payable and accrued expenses	68,622	142,155	772,111
Net cash used in operating activities	$ (7,595,567)	$ (4,577,725)	$ (50,270,097)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$ (20,924)	$ (8,313)	$ (90,176)
Purchase of short-term investments	–	(202,532)	(41,411,452)
Purchase of marketable equity securities	–	(46,200)	(46,200)
Proceeds from maturities of short-term investments	4,048,614	9,878,700	41,419,356
Organization costs	–	–	(42,165)
Net cash provided by (used in) investing activities	$ 4,027,690	$ 9,621,655	$ (170,637)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$ 2,667,234	$ –	$ 55,324,998
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	$ 2,667,234	$ –	$ 56,479,324
(Decrease) increase in cash and cash equivalents	(900,643)	5,043,930	6,038,590
Cash and cash equivalents at beginning of period	6,939,233	7,886,937	–
Cash and cash equivalents at end of period	$ 6,038,590	$ 12,930,867	$ 6,038,590
Supplemental cash flow information:			
Cash paid for interest	–	–	$ 171,473
Supplemental non-cash activities:			
Cashless exercise of stock options	$ –	$ 1,950	$ 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	2,190,979	–	$ 6,459,979

See accompanying notes to condensed financial statements.

Notes to Condensed Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. (the "Company") is developing the Delcath Percutaneous Hepatic Perfusion System, or the Delcath PHP System™ ("the System"), an innovative drug delivery device designed to treat cancers of the liver. The System provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System™ is minimally invasive and repeatable. The Company believes that the Delcath PHP System™ is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with our system is for the treatment of primary and secondary cancers of the liver. In our initial application, the Delcath PHP System™ isolates the liver from the patient's general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. The Company is currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System™ with melphalan in patients with liver cancers.

The Company's most advanced trial is a randomized Phase III NCI led multi-center study for patients with metastatic ocular and cutaneous melanoma in the liver. The FDA has granted the Delcath PHP System™ with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. The Company has also been granted four orphan drug designations, including for the drug melphalan for the treatment of patients with ocular and cutaneous melanoma. The Company began enrollment of its Phase III clinical trial in 2006 to support the FDA approval process. The enrollment for the clinical trial is complete.

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 unaudited interim condensed 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 September 30, 2009 and 2008, and cumulative from inception (August 5, 1988) to September 30, 2009. In connection with the preparation of the condensed financial statements and in accordance with the recently issued Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 855-10, the Company evaluated subsequent events after the balance sheet date of September 30, 2009 through October 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 September 30, 2009 financial statements.

Note 3: Recently Adopted Accounting Pronouncements

In January 2009, the Company adopted FASB ASC 815-10-65, which requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The adoption of FASB ASC 815-10-65 did not have a material impact on the unaudited interim condensed financial statements.

In July 2009, the Company adopted FASB ASC 855-10 which requires the Company to evaluate events occurring between the end of the quarter being reported through the date the financial statements are issued or are available to be issued.

In October 2009, the Company adopted FASB ASC 105-10, which establishes the FASB ASC as the source of authoritative principles and standards to be applied in the preparation of financial statements in conformity with GAAP. As FASB ASC is not intended to change or alter existing GAAP, it will not impact our 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 that 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 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 September 30, 2009 of $28,000 which included a gross unrealized loss of $18,200, which is included as a component of comprehensive loss.

Note 6: Stockholders' Equity

In September 2009, the Company granted 250,000 options to purchase shares of the Company's common stock to its newly appointed Chief Financial 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 ten-year stock option grant was $2.58, estimated on the date of grant using the Black-Scholes option-pricing model. These options vest ratably over two years. The expected term was estimated using a midpoint between the date of grant and the expiration date as allowed by the Simplified Method of term calculation. The weighted-average assumption of a risk free interest rate of 2.61% 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 74.97% 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 has recognized compensation expense of $26,882 for the third quarter of 2009 relating to these options.

The Company also granted 50,000 shares of restricted common stock to its newly appointed Chief Financial Officer pursuant to the terms of his employment agreement. These shares had an issuance value of $3.92 per share and vest incrementally over one year. The Company has recognized compensation expense totaling $16,333 relating to these shares.

In July 2009, the Company granted 50,000 options to its President and Chief Executive Officer pursuant to the terms of his employment agreement. These options vested immediately and 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 ten-year stock option grant was $2.05 estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date as allowed by the Simplified Method of term calculation. The weighted-average assumption of a risk free interest rate of 2.40% 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 73.12% 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 $102,615 upon grant of these options.

In July 2009, the Company granted 750,000 options to its President and Chief Executive Officer pursuant to the terms of his employment agreement. These options vest over three years and 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 ten-year stock option grant was $2.29 estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date as allowed by the Simplified Method of term calculation. The weighted-average assumption of a risk free interest rate of 2.76% 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 77.08% 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 $143,372 for the third quarter of 2009.

In July 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 $1.79, 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 allowed by the Simplified Method of term calculation. The weighted-average assumption of a risk free interest rate of 1.25% 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 86.00% 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 $89,709 upon grant of these fully vested options.

In July 2009, the Company granted 25,000 shares of restricted common stock to its former President and Chief Executive Officer pursuant to the terms of his employment agreement. These shares had an issuance value of $3.51 per share and vested immediately. The Company has recognized compensation expense totaling $87,750 relating to these shares.

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 allowed by the Simplified Method of term calculation. 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 allowed by the Simplified Method of term calculation. 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 September 30, 2009, the Company recognized compensation expense of $19,401 relating to options granted in previous years. For the nine months ended September 30, 2009, the Company recognized compensation expense of $93,258 relating to options granted in previous years.

In July 2008, the Company granted 200,000 shares of restricted 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 $121,000 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, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2,190,979 to the 2009 Warrants (see below), resulting in net proceeds of $467,559. The fair value of the 2009 Warrants on June 15, 2009 was determined 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 issued pursuant to an effective registration statement on Form S-3 (333-143280, as amended by 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 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 issued pursuant to an effective registration statement on Form S-3 (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. 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 nine month period ended September 30, 2009, the Company recorded pre-tax derivative instrument expense of $8,296,958. The resulting derivative instrument liability totaled $10,936,255 at September 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 September 30, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate of 2.18% for the 2009 Warrants and 1.45% for the 2007 Warrants, volatility of 73.74% for the 2009 Warrants and 82.45% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

Note 7: Stock Option Plans

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 nine month period ended September 30, 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	1,160,000	1.24 – 3.92	3.40	-
Expired	-	-	-	-
Exercised	-	-	-	-
Outstanding at September 30, 2009	2,620,000	$1.23 – $6.18	$3.42	5.46

Note 8: Assets and Liabilities Measured at Fair Value

Derivative Financial Instruments

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. 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 September 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 $6,032,024.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2009, aggregated by the level in the fair value hierarchy within which those measurements fall:

F-10

Assets and Liabilities Measured at Fair Value on a Recurring Basis at September 30, 2009

	Level 1	Level 2	Level 3	Balance at September 30, 2009
Assets				
Marketable equity securities	$28,000	$–	$–	$28,000
Money market funds	6,032,024	–	–	6,032,024
Total Assets	$6,060,024	$–	$–	$6,060,024
Liabilities				
Derivative financial instruments	$–	$10,936,255	$–	$10,936,255
Total Liabilities	$–	$10,936,255	$–	$10,936,255

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

Note 9: Income Taxes

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.

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 ended September 30, 2009, the Company recorded a state income tax benefit of $361,035 in the Statement of Operations. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to $250,000 per year. Of the total benefit, $173,535 relates to 2008 research and development expense credits and $187,500 relates to the estimated 2009 research and development expense credits for the first three quarters of 2009.

Note 10: Subsequent Events

As of September 30, 2009, the Company had enrolled a total of 89 patients of the expected 92-patient Phase III clinical trial. Between October 1, 2009 and October 23, 2009 the Company enrolled an additional 3 patients, bringing total enrollment to 92 patients and completing enrollment in the Phase III clinical trial. Trial enrollment will continue for the near-term to include patients that have begun the evaluation process.

On October 2, 2009, the Company announced the appointment of Dr. Krishna Kandarpa, MD, PhD, its Executive Vice President, Research & Development, and Chief Medical Officer. Dr. Kandarpa replaces Mark Morrison, MD, PhD as Chief Medical Officer.

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 unaudited interim condensed financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the year ended December 31, 2008 included in our Annual Report on 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.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains forward-looking statements that involve substantial risks and uncertainties. In some cases you can identify these statements by forward-looking words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "should," "will," and "would," or similar words. You should read forward-looking statements care because they discuss future expectations, contain projections of future results of operations or of financial position or state other "forward-looking" information. Forward-looking statements include, but are not limited to, statements about the progress and results of our research and development programs; our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing; the results and timing of our clinical trials and the commencement of futures clinical trials; and submission and timing of applications for regulatory approval. The important factors listed below, as well as any cautionary language elsewhere in this Quarterly Report on Form 10-Q and the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations described in these forward-looking statements. You should be aware that the occurrence of the events described in this Quarterly Report on Form 10-Q and in the risk factors appearing in our Annual Report on Form 10-K for the year ended December 31, 2008 could have an adverse effect on our business, results of operations and financial condition.

Any forward-looking statements in this Quarterly Report on Form 10-Q are not guarantees of future performance, and actual results, developments and business decisions may differ from those envisaged by such forward-looking statements, possibly materially. We disclaim any duty to update any forward-looking statements.

Overview

Delcath Systems, Inc. (the "Company") is developing the Delcath Percutaneous Hepatic Perfusion System, or the Delcath PHP System™ ("the System"), an innovative drug delivery device designed to treat cancers of the liver. The System provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System™ is minimally invasive and repeatable. The Company believes that the Delcath PHP System™ is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with our system is for the treatment of primary and secondary cancers of the liver. In our initial application, the Delcath PHP System™ isolates the liver from the patient's general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. The Company is currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System™ with melphalan in patients with liver cancers.

The Company's most advanced trial is a randomized Phase III NCI led multi-center study for patients with metastatic ocular and cutaneous melanoma in the liver. The FDA has granted the Delcath PHP System™ with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. The Company has also been granted four orphan drug designations, including for the drug melphalan for the treatment of patients with ocular and cutaneous melanoma. The Company began enrollment of its Phase III clinical trial in 2006 to support the FDA

approval process. The enrollment for the clinical trial is complete.

The 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. The System allows for ultra-high doses of chemotherapy agents to be directed at a patient's liver while at the same time controlling 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 System is more effective than conventional treatment at killing cancer cells and preventing new cancer cell formation.

In 2006, we began a Phase III clinical trial to support a pre-market approval and New Drug Approval ("NDA") application for use of the 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, we have negotiated and entered into research relationships with eleven centers as part of this trial, bringing the total number of 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

As of September 30, 2009, we had enrolled a total of 89 patients of the expected 92-patient trial. Between October 1, 2009 and October 23, 2009 we have enrolled an additional 3 patients, bringing total enrollment to 92 patients and completing enrollment in the Phase III clinical trial. Trial enrollment will continue for the near-term to include patients that have begun the evaluation process. In 2004, we began a multi-arm Phase II clinical trial for the use of the Delcath PHP

3

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 melanoma that has spread to the liver who have received prior regional treatment with melphalan. Based on promising initial clinical results, we focused our efforts on enrolling patients for the treatment of metastatic neuroendocrine tumors; that arm of the trial has 25 patients enrolled.

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 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 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.

We expect that the amount of capital required to complete our Phase III clinical trial, prepare the Company's submission to the FDA, and finalize our new manufacturing facility in upstate New York will continue to increase over the coming months. We believe that we have sufficient capital for operations through 2009.

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.

Recent Developments

On September 1, 2009, the Company entered into a lease with option to purchase (the "Lease") with Fitzgerald Brothers Beverages, Inc. (the "Landlord"), for the real property and free standing building thereon, containing approximately 10,320 square feet located at 566 Queensbury Avenue, Kingsbury, NY (the "Facility"). The Facility will house the Company's manufacturing operations. The term of the Lease commenced on September 1, 2009. Base rent on the Lease is $51,600 per year, payable in equal monthly installments of $4,300 on the first day of each month. The Company has an option to purchase the Facility upon delivery of written notice to the Landlord at least 120 days prior to expiration of the Lease term. The purchase price for the Facility is $400,000 if the Company acquires the Facility by September 1, 2010, $425,000 if the Company acquires the Facility by September 1, 2011, and $440,000 if the Company acquires the Facility by September 1, 2012.

Results of Operations

Three Months Ended September 30, 2009 and September 30, 2008

We have operated at a loss for our entire history. We had a net loss for the three months ended September 30, 2009, of $7,585,904, which is a $6,708,047 increase in the net loss for the same period in 2008. The increase in net loss is due to a $5,111,549 increase in derivative instrument expense related to the Warrants, as well as an increase of $1,606,378 in total costs.

General and administrative expenses increased by 153.2%, from $589,900 during the three months ended September 30, 2008 to $1,493,490 for the three months ended September 30, 2009, an increase of $903,590. A significant portion of this increase is related to satisfaction of the Company's obligations under a separation agreement with its former President and CEO, and the retention of a new President and Chief Executive Officer and a Chief Financial Officer.

For the three months ended September 30, 2009, research and development expenses increased by 43.3%, from $1,624,379 during the third quarter of 2008 to $2,327,167, an increase of $702,788. This increase is related to an increase in treatments performed in the third quarter of 2009 as compared to the third quarter of 2008, as well as the recent personnel changes discussed in the preceding paragraph.

Interest income shown is from our money market. During the three months ended September 30, 2009, the Company had interest income of $3,054, as compared to $55,674 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.

Nine Months Ended September 30, 2009 and September 30, 2008

We had a net loss of $16,359,010 for the nine months ended September 30, 2009. This compares to a net loss of $4,355,877 for the same period of 2008. The increase of $12,003,133 in net loss is related to a $9,104,305 increase in derivative instrument expense related to the Warrants, as well as a $3,053,895 increase in total costs and expenses.

For the nine months ended September 30, 2009, we incurred $2,513,366 in expenses related to our general and administrative operations. This is a 45.3% increase from the same period in 2008, when we incurred $1,730,040 in general and administrative expenses. A significant portion of this increase is related to satisfaction of the Company's obligations under a separation agreement with its former President and CEO, and the retention of a new President and Chief Executive Officer and a Chief Financial Officer.

For the nine months ended September 30, 2009, research and development costs increased by 61.2%, from $3,712,823 for the first nine months of 2008 to $5,983,392 for the nine months ended September 30, 2009, a $2,270,569 increase. The addition of several centers and the increased rate of enrollment in connection with our Phase III clinical trial has led to a significant increase in treatments performed and all related expenses in the first nine months of 2009 as compared to the first nine months of 2008. With full enrollment in the Phase III clinical trial, the Company anticipates spending directed towards the Phase III clinical trial will begin to steady, while expenses related to the Company's preparation for FDA submission and the development of our newly-leased manufacturing facility in Kingsbury, New York will begin accelerating.

Interest income shown is from the Company's money market account and investment in various certificates of deposit. During the nine months ended September 30, 2009, the Company had interest income of $71,982, as compared to interest income of $279,639 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. As we seek FDA approval and get our product to market we expect that our capital expenditures will increase significantly.

At September 30, 2009, we had cash and cash equivalents of $6,038,590, as compared to $6,939,233 at December 31, 2008. Nearly all of our available funds are invested in money market accounts.

During the nine months ended September 30, 2009, we used $7,595,567 of cash in our operating activities. This amount compares to $4,577,725 used in our operating activities during the comparable nine month period in 2008. The increase of $3,017,842, or 65.9%, is primarily due to the recent personnel changes discussed above and the accelerated clinical trial development costs related to all facets of the Phase III clinical trials and the Delcath PHP System™. We expect that our cash allocated to operating activities will continually increase as we aggressively move toward completion of our first Phase III clinical trial, outfit and fully staff our new facility in Kingsbury. New York, and continue to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our operating activities through 2009.

At September 30, 2009, the Company's accumulated deficit was approximately $63.7 million. Because our business does not generate any positive cash flow from operating activities, we will 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 unaudited interim condensed financial statements contained in this Quarterly Report on 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, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2,190,979 to the 2009 Warrants (see below), resulting in net proceeds of $467,559. 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 issued pursuant to an effective registration statement on Form S-3 (333-143280, as amended by 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.

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 FASB ASC 740 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.

The Company has adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). 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 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 FASB ASC 718. 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 FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. FASB ASC 820 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 FASB ASC 820 did not have a material effect on the carrying values of the Company's assets.

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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 that 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 ended 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 September 30, 2009. The investment is classified as an available for sale security and had a fair value on September 30, 2009 of $28,000, which included a gross unrealized loss of $18,200, 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, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2,190,979 to the 2009 Warrants, resulting in net proceeds of $467,559. 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 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. 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 nine month period ended September 30, 2009, the Company recorded pre-tax derivative instrument expense of $8,296,958. The resulting derivative instrument liability totaled $10,936,255 at September 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 September 30, 2009 was determined by using the Black-Scholes model assuming a risk free interest rate

9

of 2.18% for the 2009 Warrants and 1.45% for the 2007 Warrants, volatility of 73.74% for the 2009 Warrants and 82.45% 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 SEC's rules and forms. 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 and principal financial 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.

PART II:

OTHER INFORMATION

Item 1. Legal Proceedings

Not Applicable.

Item 1A. Risk Factors

Our 2008 Form 10-K, in Part 1, Item 1A. "Risk Factors", contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition. There have been no material changes in these risk factors since such disclosure.

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

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

10

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

Not Applicable.

Item 5. Other Information

Not Applicable.

Item 6. Exhibits

10.1 Employment Agreement dated July 6, 2009 between Eamonn P. Hobbs and Delcath Systems, Inc. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on July 7, 2009 and incorporated herein by reference.

10.2 Stock Option Grant Letter dated July 6, 2009 – Eamonn P. Hobbs. Filed as Exhibit 10.4 to our Current Report on Form 8-K filed on September 17, 2009 and incorporated herein by reference.

10.3 Stock Option Grant Letter dated July 6, 2009 – Eamonn P. Hobbs. Filed as Exhibit 10.5 to our Current Report on Form 8-K filed on September 17, 2009 and incorporated herein by reference.

10.4 Separation and General Release Agreement between Richard L. Taney and Delcath Systems, Inc. Filed as Exhibit 10.2 to our Current Report on Form 8-K filed on July 7, 2009 and incorporated herein by reference.

10.5 Lease with Option to Purchase dated September 1, 2009, between Delcath Systems, Inc. and Fitzgerald Brothers Beverages, Inc. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 3, 2009 and incorporated herein by reference.

10.6 Employment Agreement dated September 13, 2009 between David A. McDonald and Delcath Systems, Inc. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 17, 2009 and incorporated herein by reference.

10.7 Stock Option Grant Letter dated September 14, 2009 – David A. McDonald. Filed as Exhibit 10.2 to our Current Report on Form 8-K filed on September 17, 2009 and incorporated herein by reference.

10.8 Restricted Stock Agreement dated September 14, 2009 – David A. McDonald. Filed as Exhibit 10.3 to our Current Report on Form 8-K filed on September 17, 2009 and incorporated herein by reference.

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.

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.

October 23, 2009

DELCATH SYSTEMS, INC.
(Registrant)

David A. McDonald
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

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