DELCATH SYSTEMS INC
Form 10-Q
October 24, 2008

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, 2008

[ ] 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 [ ]

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 [x]

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 [x]

As of October 21, 2008, 25,335,254 shares of the Company's common stock, $0.01 par value, were issued and outstanding

DELCATH SYSTEMS, INC.
(A Development Stage Company)

DELCATH SYSTEMS, INC.

Index

DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:
FINANCIAL INFORMATION

ItemCondensed Financial Statements (Unaudited)
1.

Index to Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Balance Sheets

	September 30, 2008 (Unaudited)	December 31, 2007 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$12,930,867	$7,886,937
Investments – treasury bills	202,532	9,878,700
Investments – marketable equity securities	38,000	-
Prepaid expenses	260,347	325,452
Total current assets	13,431,746	18,091,089
Property and equipment, net	18,955	15,037
Total assets	$13,450,701	$18,106,126
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$267,433	$125,278
Derivative instrument liability	744,653	1,552,000
Total current liabilities	1,012,086	1,677,278
Stockholders' equity		
Common stock, $.01 par value; 70,000,000 shares authorized	253,353	252,593
Additional paid-in capital	56,999,617	56,626,533
Deficit accumulated during development stage	(44,806,155)	(40,450,278)
Accumulated other comprehensive loss	(8,200)	–
Total stockholders' equity	12,438,615	16,428,848
Total liabilities and stockholders' equity	$13,450,701	$18,106,126

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 (August 5, 1988) to September 30,
	2008	2007	2008	2007	2008
Costs and expenses:					
General and administrative expenses	$589,900	$609,759	$1,730,040	$2,183,043	$21,821,450
Research and development costs	1,624,379	1,125,573	3,712,823	3,208,963	27,731,904
Total costs and expenses	$2,214,279	$1,735,332	$5,442,863	$5,392,006	$49,553,354
Operating loss	(2,214,279)	(1,735,332)	$(5,442,863)	$(5,392,006)	$(49,553,354)
Derivative instrument income (expense)	1,280,748	(78,000)	807,347	(78,000)	3,524,347
Interest income	55,674	101,755	279,639	305,301	2,766,432
Other income	–	–	–	–	126,500
Interest expense	–	–	–	–	(171,473)
Net loss	$(877,857)	$(1,711,577)	$(4,355,877)	$(5,164,705)	$(43,307,548)
Common share data:					
Basic and diluted loss per share	$(0.03)	$(0.08)	$(0.17)	$(0.24)	
Weighted average number of shares of common stock outstanding	25,334,244	21,630,349	25,285,366	21,331,461	

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		Additional Paid	Accumulated Other Comprehensive	Deficit Accumulated During Development		Comprehensive
	No. of Shares	Amount	in Capital	Loss	Stage	Total	loss
Balance at December 31, 2007	25,259,284	$252,593	$56,626,533	-	$(40,450,278)	$16,428,848	
Compensation expense for issuance of stock options	-	-	149,861	-	-	149,861	
Compensation expense for issuance of restricted stock			40,333			40,333	
Compensation expense for issuance of common stock to management and directors for services	75,000	750	180,950	-	-	181,700	
Cashless exercise of stock options	970	10	1,940	-	-	1,950	
Components of comprehensive loss:							
Change in unrealized loss on investments	-	-	-	$(8,200)	-	(8,200)	$(8,200)
Net loss	-	-	-	-	(4,355,877)	(4,355,877)	(4,355,877)
Total comprehensive loss							$(4,364,077)
Balance at September 30, 2008	25,335,254	$253,353	$56,999,617	$(8,200)	$(44,806,155)	$12,438,615	

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,
	2008	2007	2008
Cash flows from operating activities:			
Net loss	$(4,355,877)	$(5,164,705)	$(43,307,548)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	149,861	1,339,776	5,130,581
Restricted stock compensation expense	40,333	–	40,333
Stock and warrant compensation expense issued for legal settlement, consulting services	183,650	211,250	1,040,361
Depreciation expense	4,395	3,020	50,295
Amortization of organization costs	–	–	42,165
Derivative liability fair value adjustment	(807,347)	78,000	(3,524,347)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	65,105	(191,499)	(260,347)
Increase (decrease) in accounts payable and accrued expenses	142,155	(560,050)	267,433
Net cash used in operating activities	$(4,577,725)	$(4,284,208)	$(40,521,074)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$(8,313)	$(15,641)	$(69,252)
Purchase of short-term investments	(202,532)	–	(37,573,274)
Purchase of marketable equity securities	(46,200)	–	(46,200)
Proceeds from maturities of short-term investments	9,878,700	1,856,762	37,370,742
Organization costs	–	–	(42,165)
Net cash provided by (used in) investing activities	$9,621,655	$1,841,121	$(360,149)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$–	$14,652,450	$52,657,764
Repurchases of common stock	–	–	(51,103)
Dividends paid on preferred stock	–	–	(499,535)
Proceeds from short-term borrowings	–	–	1,704,964
Net cash provided by financing activities	$–	$14,652,450	$53,812,090
Increase in cash and cash equivalents	5,043,930	12,209,363	12,930,867
Cash and cash equivalents at beginning of period	7,886,937	6,289,723	–
Cash and cash equivalents at end of period	$12,930,867	$18,499,086	$12,930,867
Supplemental cash flow information:			
Cash paid for interest	–	–	$171,473
Supplemental non-cash activities:			
Cashless exercise of stock options	$1,950	$450,999	$544,116

Conversion of debt to common stock	–	–	$1,704,964
Common stock issued for preferred stock dividends	–	–	$999,070
Conversion of preferred stock to common stock	–	–	$24,167
Common stock issued as compensation for stock sale	–	–	$510,000
Fair value of warrants issued	–	–	$4,269,000

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements

NoteDescription of Business
1:

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 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 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 expects it to be fully enrolled in 2009. In 2004, the Company began a multi-arm Phase II clinical trial for use of the Delcath 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 colorectal cancer and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the FDA concerning a clinical trial that will focus on the effectiveness of the Delcath System in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September the Company received a conditional approval from the FDA to begin working on that trial. To date, the Delcath System has not been approved by the FDA.

NoteBasis of Financial Statement Presentation
2:

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended September 30, 2008 and 2007, and cumulative from inception (August 5, 1988) to September 30, 2008.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2007, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission (the "SEC") on March 12, 2008 (the "2007 Form 10-K").

Note 3: Accounting Pronouncements Not Yet Adopted

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"), which changes the disclosure requirements for derivative instruments and hedging activities. SFAS 161 requires enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133, "Accounting for Derivative Instruments

and Hedging Activities" and its related

DELCATH SYSTEMS, INC.
(A Development Stage Company)

interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. This Statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company has not yet determined the effect, if any, that SFAS 161 will have on its condensed financial statements.

NoteCosts and Expenses
4:

Research and Development Costs

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

General and Administrative Costs

General and administrative costs include salaries and related expenses for our executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Note 5: Investment in Marketable Equity Securities

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc., (“AEMD”) a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of this agreement, the Company received 100,000 shares of restricted common stock of AEMD. The Company allocated $46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement and then discounting that value due to certain sale restrictions on the stock being held. At September 30, 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 September 30, 2008 of $38,000 which included a gross unrealized loss of $8,200, which is included as a component of comprehensive loss.

NoteStockholders’ Equity
6:

During the nine months ended September 30, 2008, there were several events that effected stockholders’ equity.

The per share weighted average fair value of stock options granted to two employees who commenced employment in June 2007 that will vest incrementally over three years during the respective terms of employment was:

(i) with respect to the first employee, $1.92 for options with a grant date in April 2007 (the date of acceptance of the offer of employment) with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares); and

F-6

DELCATH SYSTEMS, INC.
(A Development Stage Company)

(ii) with respect to the second employee, (a) $1.75 for options with a grant date in May 2007 (the date of acceptance of the offer of employment) with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares), and (b) $1.22 for options with a grant date of May 2007 (the date of acceptance of the offer of employment) with an exercise price equal to 150% of the fair value of the common stock at the date of grant (options for an aggregate of 25,000 shares).

The per share weighted average fair value of such options was estimated on the date of acceptance using the Black-Scholes option-pricing model. The expected term was estimated to be the full three year vesting period as the Company does not have a calculable history of forfeitures by employees granted options. The weighted-average assumption of a risk free interest rate of 4.60% 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 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends on common stock in the past nor does it expect to pay dividends in the future. The Company has recognized compensation expense of $53,501 in 2008 relating to these option grants.

The per share weighted average fair value of five-year stock options granted to the President and Chief Executive Officer in January 2008 was $0.68 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 50,000 shares), 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 Statement of Financial Accounting Standards No. 123R, "Share-Based Payment". The weighted-average assumption of a risk free interest rate of 2.89% 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 60.3% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The Company recognized compensation expense totaling $33,873 upon grant of these fully vested options.

The per share weighted average fair value of five-year stock options granted to an employee in May 2008 that will vest incrementally over three years was $0.94 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 20,000 shares), 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 for each vesting tranche as required by the Simplified Method of term calculation in accordance with Statement of Financial Accounting Standards No. 123R, "Share-Based Payment". The weighted-average assumption of a risk free interest rate of 2.53% 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 68.81% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The Company has recognized compensation expense of $2,613 in 2008 relating to these option grants.

The per share weighted average fair value of five-year stock options granted to a new employee in June 2008 that will vest after twelve months of employment was (a) $1.08 for options with an exercise price

F-7

DELCATH SYSTEMS, INC.
(A Development Stage Company)

equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares) and (b) $0.82 for options with an exercise price equal to 150% of the fair value of the common stock at the date of grant (options for an aggregate of 20,000 shares) 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 for each vesting tranche as required by the Simplified Method of term calculation in accordance with Statement of Financial Accounting Standards No. 123R, "Share-Based Payment". The weighted-average assumption of a risk free interest rate of 3.27% 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 67.35% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The Company has recognized compensation expense of $5,843 in 2008 relating to these option grants.

In June 2008, the Company issued common stock to the President and Chief Executive Officer in accordance with his Employment Agreement and to the Directors totaling 50,000 shares that had issuance values between $2.19 and $2.47. The total compensation expense recorded as a result of the common stock issued was $120,700.

The per share weighted average fair value of five-year stock options granted to the President and Chief Executive Officer in July 2008 was $1.08 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 50,000 shares), 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 Statement of Financial Accounting Standards No. 123R, "Share-Based Payment". The weighted-average assumption of a risk free interest rate of 2.74% 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 70.6% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The Company recognized compensation expense totaling $54,031 upon the grant of these fully vested options.

In July 2008 the Company issued common stock to the President and Chief Executive Officer in accordance with his Employment Agreement totaling 25,000 shares that had an issuance value of $2.44. As a result, the common stock issued, the Company recorded compensation expense of $61,000.

In July 2008, in accordance with a letter agreement with the new Chief Medical Officer, the Company issued common stock totaling 200,000 shares that will vest incrementally over three years that had an issuance value of $2.42. As a result of the common stock issued, the expense recorded will total $40,333 per quarter during the period of vesting.

In September 2008, a cashless exercise of 15,000 options with an exercise price of $2.01 per share resulted in the issuance of 970 shares of common stock.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The

F-8

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Company allocated $4,269,000 of the total proceeds to warrants (see below). The warrants are exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280).

The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances, including its inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature. Accordingly, the warrants have been accounted for as derivative instrument liabilities that are subject to mark-to-market adjustment in each period. As a result, for the three and nine month periods ended September 30, 2008, the Company recorded pre-tax derivative instrument income of $1,280,748 and $807,347, respectively. The resulting derivative instrument liability totaled $744,653 at September 30, 2008. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 2.63%, volatility of 68.52% and an expected life equal to the September 24, 2012 contractual life of the warrants.

NoteStock Option Plan
7:

The Company has adopted the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" ("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). Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant. The Company also followed the disclosure requirements of SFAS 123 as amended by SFAS 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." 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.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of our common stock at the date of the grant. The Company estimates the fair value of stock options using a Black-Scholes valuation model. Key inputs used to estimate the fair value of stock

DELCATH SYSTEMS, INC.
(A Development Stage Company)

options include the exercise price of the award, the expected post-vesting option life, the expected volatility of our stock over the option's expected term, the risk-free interest rate over the option's expected term, and our expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

The Company established the 2000 Stock Option Plan, the 2001 Stock Option Plan and the 2004 Stock Incentive Plan (collectively, the "Plans") under which stock options, stock appreciation rights, restricted stock, and stock grants may be awarded. A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Compensation and Stock Option Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the terms and conditions of each award, the option price and the duration of each award.

During 2000, 2001 and 2004, respectively, the Plans became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for the nine-month period ended September 30, 2008 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2007	1,140,000	$1.88 – $7.14	$4.54	3.96
Granted	190,000	1.74 – 3.45	2.27	
Expired	(5,000)	3.59	3.59	
Exercised	(15,000)	1.88	1.88	
Outstanding at September 30, 2008	1,310,000	$1.74 – $7.14	$4.24	3.60

NoteAssets and Liabilities Measured at Fair Value
8:

Derivative financial instruments

Currently, the Company has allocated proceeds of warrants issued in connection with a private placement that were classified as a liability and accounted for as a derivative instrument in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock". The valuation of the warrants is determined using the Black-Scholes model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the inputs associated with fair value determination are readily observable and as a result the instrument is classified within Level 2 of the fair-value hierarchy.

Marketable Equity Securities

The Company owns 100,000 shares of common stock of AEMD. At September 30, 2008, the valuation of such stock is determined utilizing the current quoted market price of AEMD due to the selling

DELCATH SYSTEMS, INC.
(A Development Stage Company)

restrictions as stated in the agreement to purchase these shares having lapsed during the three month period ending September 30, 2008. The Company has determined that the inputs associated with the fair value determination are readily observable and as a result the instrument was classified within Level 1 of the fair-value hierarchy.

Money Market Funds and Treasury Bills

Cash and cash equivalents includes a money market account valued at $12,930,867. The Company also has a U.S. treasury bill totaling $202,532.

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

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2008, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis at September 30, 2008

	Level 1	Level 2	Level 3	Balance at September 30, 2008
Assets				
Marketable equity securities	$ $38,000	$ —$	—$	38,000
Money market funds	12,930,867			12,930,867
Treasury bills	202,532			202,532
Liabilities				
Derivative financial instruments	$ —$	744,653 $	—$	744,653

The Company does not have any fair value measurements using significant unobservable inputs (Level 3) as of September 30, 2008.

NoteIncome Taxes
9:

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" ("FIN No. 48"), on January 1, 2007. FIN No. 48 requires that the impact of tax positions be recognized in the financial statements if they are more

F-11

likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the financial statements in the 2007 Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in their balance sheet under the provisions of FIN No. 48.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service or any states in connection with income taxes. The periods from December 31, 2003 to December 31, 2007 remain open to examination by the U.S. Internal Revenue Service and state authorities.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed and consolidated financial statements and notes thereto contained in Item 1 of Part I of this Form 10-Q and our audited "financial statements and notes thereto as of and for the year ended December 31, 2007" included in our Form 10-K for the year ended December 31, 2007 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, 2007. 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 System, for the treatment of tumors of the liver. Based on human clinical data, we believe that the Delcath System allows physicians to deliver significantly higher chemotherapy doses to the liver than could be administered by conventional intravenous delivery.

The Delcath System is a disposable kit consisting of various catheters, filters, and a tubing circuit used during cancer treatment to isolate the liver from the patients 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 System is more effective than conventional treatment at killing cancer cells and preventing new cancer cell formation.

2

DELCATH SYSTEMS, INC.
(A Development Stage Company)

In 2006 we began a Phase III clinical trial to support a pre-market approval application for use of the Delcath System with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is being conducted under the Food and Drug Administration's ("FDA") Special Protocol Assessment ("SPA"). Patients enrolled in this study currently receive treatment at the National Cancer Institute, or NCI, which serves as the coordinating center for this multi-center trial. The trial is currently approved for expansion to a maximum of 15 centers. In April 2008, the Institutional Review Board of the University of Maryland Medical Center agreed to participate in our Phase III study. In June 2008, St. Luke's Cancer Center, the Albany Medical Center, the Atlantic Melanoma Center of Atlantic Health and the University of Texas Medical Branch joined this clinical trial. In the third quarter, Swedish Medical Center of Colorado, John Wayne Cancer Institute, Providence Health Systems, and Moffitt Cancer Center agreed to join the clinical trial which brings the total to ten centers. Each of the centers Institutional Review Board ("IRB") has approved our treatment protocol. Critical to expediting completion of this trial, the Western International Review Board, or WIRB, has also approved our protocol. The WIRB, which provides review services for more than 100 institutions (academic centers, hospitals, networks and in-house biotech research) in all 50 states and internationally, will help accelerate the internal review process at a number of the hospitals currently participating in the study. As of September 30, 2008 we have enrolled a total of 40 patients of the expected 92 patient trial. We expect to complete patient enrollment in this study in 2009. Once the FDA grants approval, we plan to conduct additional pre-clinical and clinical trials on the use of the Delcath System with other chemotherapy agents used to treat cancer in the liver and seek additional FDA pre-market approvals.

In 2004 we began a multi-arm Phase II clinical trial for the use of the Delcath System with melphalan in the treatment of hepatocellular carcinomas as well as neuroendocrine and adenocarcenoma 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 22 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 colorectal cancer and primary liver cancer will be refocused so as to optimize the progress of those arms of the trial. The Company has entered into a dialogue with the FDA concerning a clinical trial that will focus on the effectiveness of the Delcath System in administering high-dose doxorubicin as compared with standard systemic treatment with sorafenib for the treatment of primary liver cancer. In September the Company received a conditional approval from the FDA to begin working on that trial.

The successful development of the Delcath 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 System has not yet been approved by the FDA and may not be marketed in the United States without FDA pre-market approval.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

During the next twelve months we plan to hire additional personnel to support the development of the Delcath System. In June 2008 and July 2008 we hired two senior executives. We hired a Chief Medical Officer to oversee the expansion of clinical activity, moving us towards the conclusion of our first Phase III clinical trial. We also hired a Senior Vice President for Regulatory Affairs and Quality Systems, a position newly created to manage the extensive FDA process. We expect that as a result of these efforts our expenditures during the next twelve months will increase significantly. 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 are a development stage company, and since our inception we have raised approximately $52.7 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses for the foreseeable future.

At our anticipated pace of development of the Delcath System, during the next twelve months we expect to incur expenses of approximately $9.5 million. We believe that we currently have sufficient capital that will take operations through 2009 and allow us to substantially advance our ongoing Phase II and Phase III trials. However, we cannot be assured that we will obtain FDA approval for our Delcath System, that we will have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for any of our products.

Results of Operations for the Nine Months Ended September 30, 2008

We have operated at a loss for our entire history. We had a net loss for the nine months ended September 30, 2008, of $4,355,877, which is an $808,828 decrease in the net loss for the same period in 2007. The decrease in net loss in 2008 is mainly attributable to $807,347 of derivative instrument income.

General and administrative expenses decreased from $2,183,043 during the nine months ended September 30, 2007, to $1,730,040 for the nine months ended September 30, 2008, or $453,003, a 20.8% change. This decrease is primarily attributed to the additional expenses incurred in 2007 by the cashless exercise of options by outgoing Directors, expenses incurred in issuing options in 2007 to new Directors, and the higher legal fees paid last year as part of the final resolution of various legal matters.

During the nine months ended September 30, 2008, we incurred $3,712,823 in research and development costs, as compared to $3,208,963 during the first quarter of 2007, an increase of $503,860. While we have incurred increases in expenses primarily due to exploring new and improved filter technology to remove current and future therapeutic agents that can be used with the Delcath PHP System, we have also expanded our clinical trials to a total of ten sites which has required additional fees for IRB approvals, patient preparation costs, and clinical trial set-up expenses.

Interest income shown is from our money market and Treasury bill and note investments. During the nine months ended September 30, 2008, the Company had interest income of $279,639, as compared to interest income of $305,301, or an 8% change, for the same period in 2007. This decrease is due to the investment of the net proceeds from the sale of our common stock and warrants that was received during

4

the third quarter of fiscal 2007 but a reduction in invested funds due to their use in clinical trials and a reduced interest rate from last year.

Results of Operations for the Three Months Ended September 30, 2008

We had a net loss for the three months ended September 30, 2008, of $877,857, which is $833,720 less than the net loss from continuing operations for the same period in 2007. This decrease is primarily due to the derivative instrument income as discussed above.

General and administrative expenses decreased from $609,759 during the three months ended September 30, 2007, to $589,900 for the three months ended September 30, 2008. The cashless exercise of options by an outgoing member of the Board of Directors in 2007 resulted in additional charges to general operations.

During the three months ended September 30, 2008, we incurred $1,624,379 in research and development costs, as compared to $1,125,573 during the corresponding period in 2007. Increased expenses incurred this year in exploring new and improved filter technology along with accelerated clinical development costs relating to all facets of the Delcath drug delivery system is offset against higher expenses incurred in 2007 as part of the option activity as explained above.

Interest income shown is from our money market and Treasury note investments. During the three months ended September 30, 2008, the Company had interest income of $55,674, as compared to interest income of $101,755 for the same period in 2007. This decrease is primarily due to a substantially reduced interest earning rate on our investments together with the reduction in investment funds due to their use in expanding our clinical trials. There was no other income during the three months ended September 30, 2008 or the comparable period in 2007.

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 September 30, 2008, we had cash and cash equivalents of $12,930,867, as compared to $7,886,937 at December 31, 2007 and $18,499,086 at September 30, 2007. Nearly all of our available funds are invested in money market accounts, which are reflected in our financial statements as part of “Cash and Cash Equivalents.”

5

DELCATH SYSTEMS, INC.
(A Development Stage Company)

During the nine months ended September 30, 2008, we used $4,577,725 of cash in our operating activities. This amount compares to $4,284,208 used in our operating activities during the comparable nine-month period in 2007. The increase of $293,517, or 6.9%, is primarily due to accelerated clinical development costs relating to all facets of the Delcath drug delivery system. We expect that our cash allocated to operating activities will increase significantly as we aggressively move toward the full enrollment and completion of our first Phase III clinical trial, and continue to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our current clinical trials through 2009. Even in light of potential increased expenditures, we believe that our cash and cash equivalents will be adequate to satisfy our capital needs through at least the next 12 months.

At September 30, 2008, the Company's accumulated deficit was approximately $ 44.8 million. Because our business does not generate any positive cash flow from operating activities, we will likely need to raise additional capital to develop our product beyond the current clinical trials or to fund development efforts relating to new products. We anticipate that we could raise additional capital in the event that we find it in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when we need it, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from those planned because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003 along with our registered direct offering in 2007. Please see the detailed discussion of our various sales of securities described in Note 2 to our 2007 Form 10-K. Over the last 18 months, we received approximately $1.3 million on exercise of warrants and options, and approximately $13.3 million from a registered direct offering we completed in 2007.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to our financial statements contained in our 2007 Form 10-K. We are still in the development stage and have no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore have very limited opportunities to choose among accounting policies or methods. In many cases, we must use an accounting policy or method because it is the only policy or method permitted under GAAP.

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

We consider the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying SFAS No. 109, "Accounting for Income Taxes," management estimates future taxable income

6

DELCATH SYSTEMS, INC.
(A Development Stage Company)

from operations and tax planning strategies in determining if it is more likely than not that we will realize the benefits of our deferred tax assets. Management believes the Company does not have any uncertain tax positions as defined under FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109."

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

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

SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

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

7

DELCATH SYSTEMS, INC.
(A Development Stage Company)

ItemQuantitative and Qualitative Disclosures about Market Risk
3.

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

In January 2008, the Company entered into a research and development agreement with 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. During the third quarter ending September 30, 2008, the restriction on the common stock held lapsed and as a result the fair value of the stock is calculated using the closing stock price (unadjusted) at September 30, 2008. The investment is classified as an available for sale security and had a fair value on September 30, 2008 of $38,000, which included a gross unrealized loss of $8,200, 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 in the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract. In 2007, the Company completed the sale of 3,833,108 shares of its Common Stock and the issuance of warrants to purchase 1,916,554 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to warrants. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280). The $4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances; including the Company's inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature in certain circumstances. Accordingly, the warrants have been accounted for as derivative instrument liabilities, which are subject to mark-to-market adjustment in each period. As a result, for the nine month period ended September 30, 2008, the Company recorded pre-tax derivative instrument income of $807,347. The resulting derivative instrument liability totaled $744,653 at September 30, 2008. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 2.63%, volatility of 68.52% and an expected life equal to the September 24, 2012 contractual life of the warrants.

ItemControls and Procedures
4.

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

been effective.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

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

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

PART II:
OTHER INFORMATION

ItemLegal Proceedings
1.

Delcath and M.S. Koly (former CEO, President, Treasurer and Director of Delcath) filed a libel complaint in August 2005 against Elizabeth Enney ("Enney") in the United States District Court for the District of Connecticut involving communications by Enney concerning Delcath and Koly to the Rolls Royce Owners Club ("RROC") in which both Koly and Enney were members (the "First Connecticut Action). In May 2006, the libel claims were dismissed without prejudice for lack of personal jurisdiction. In July 2006, Delcath and Koly filed a similar libel lawsuit in the United States District Court for the Northern District of Georgia (the "Georgia District Court"). On April 19, 2007, the Georgia District Court dismissed the action, and denied Enney's motion for sanctions. Enney appealed. Delcath and Koly did not appeal.

On March 7, 2008, the Eleventh Circuit Court of Appeals reversed the denial of Enney's motion for sanctions, and remanded the action to the Georgia District Court for further proceedings to determine the amount of sanctions. Enney has requested sanctions in excess of $400,000. A hearing was held on September 23, 2008. On September 25, 2008 the Georgia District Court ordered all parties in the George District Court action and a related action between Enney and the RROC (in which Delcath is not a party) to mediation to attempt to resolve the parties' various claims.

On July 29, 2008 Enney filed a complaint in the United States District Court for the District of Connecticut against Delcath, Donna Newman (Delcath's and Koly's former counsel), and David Foltz (Delcath's and Koly's former counsel) alleging abuse of process, vexatious litigation and violations of Connecticut's Unfair Trade Practices Act (the "New Connecticut Action"), based on Koly's and Delcath's prosecution of the original libel suit in Connecticut. The complaint seeks damages in excess of $500,000, and punitive damages.

Delcath has been vigorously contesting the sanctions proceeding in the Georgia District Court and the claims in the New Connecticut Action. Although the ultimate effect of these matters is difficult to

9

predict, management believes that their resolution will not have a material adverse effect on the Company'financial statements. However, no assurance can be given that Delcath will prevail in either action.

ItemRisk Factors
1A.

Our 2007 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.

None.

Item Defaults upon Senior Securities
3.

None.

ItemSubmission of Matters to a Vote of Security Holders
4.

None.

ItemOther Information
5.

None.

ItemExhibits
6.

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

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

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

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

10

DELCATH SYSTEMS, INC.
(A Development Stage Company)

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 24, 2008

DELCATH SYSTEMS, INC.
(Registrant)

/s/ Paul M. Feinstein
Paul M. Feinstein
Chief Financial Officer and Treasurer
(on behalf of the registrant and as the principal financial and accounting officer of the registrant)

DELCATH SYSTEMS, INC.
(A Development Stage Company)

EXHIBIT INDEX

Exhibit No.	Description
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