DELCATH SYSTEMS INC
Form 10-Q
May 09, 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 March 31, 2008

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

For the transition period from ____________ to ____________

Commission file number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	06-1245881
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

600 Fifth Avenue, 23rd Floor, New York, NY 10020
(Address of principal executive offices)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	x
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

As of May 5, 2008, 25,259,284 shares of the Company’s common stock, $0.01 par value, were issued and outstanding

DELCATH SYSTEMS, INC.

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PART I:
FINANCIAL INFORMATION

Item 1: Condensed Financial Statements (Unaudited)

Index to Financial Statements

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

		March 31, 2008 (Unaudited)		December 31, 2007 (Audited)
Assets				
Current assets				
Cash and cash equivalents	$	16,244,378	$	7,886,937
Investments - treasury bills		205,454		9,878,700
Investments - marketable equity securities		37,100		-
Prepaid expenses		338,684		325,452
Total current assets	$	16,825,616	$	18,091,089
Property and equipment, net		21,884		15,037
Total assets	$	16,847,500	$	18,106,126
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable and accrued expenses		80,042		125,278
Derivative instrument liability		1,353,749		1,552,000
Total current liabilities	$	1,433,791	$	1,677,278
Commitments and contingencies		-		-
Stockholders' equity				
Common stock, $.01 par value; 70,000,000 shares authorized	$	252,593	$	252,593
Additional paid-in capital		56,678,240		56,626,533
Deficit accumulated during development stage		(41,508,024)		(40,450,278)
Accumulated other comprehensive loss		(9,100)		-
Total stockholders' equity	$	15,413,709	$	16,428,848
Total liabilities and stockholders' equity	$	16,847,500	$	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 March 31, 2008	Three Months Ended March 31, 2007	Cumulative from Inception (August 5, 1988) to March 31, 2008
Costs and expenses:			
General and administrative expenses	$ 441,004	$ 500,819	$ 20,532,415
Research and development costs	988,956	888,951	25,008,037
Total costs and expenses	$ 1,429,960	$ 1,389,770	$ 45,540,452
Operating loss	$ (1,429,960)	$ (1,389,770)	$ (45,540,452)
Derivative instrument income	198,251	-	2,915,251
Interest income	173,963	115,656	2,660,755
Other income	-	-	126,500
Interest expense	-	-	(171,473)
Net loss	$ (1,057,746)	$ (1,274,114)	$ (40,009,419)
Common share data:			
Basic and diluted loss per share	$ (0.04)	$ (0.06)	
Weighted average number of shares of common stock outstanding	25,259,284	21,004,943	

See accompanying notes to condensed financial statements.

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

	Three Months Ended March 31, 2008	Three Months Ended March 31, 2007	Cumulative from inception (Aug. 5, 1988) to March 31, 2008
Cash flows from operating activities:			
Net loss	$ (1,057,746)	$ (1,274,114)	$ (40,009,418)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	51,707	-	5,032,427
Stock and warrant compensation expense issued for legal settlement, consulting services	-	-	856,711
Depreciation expense	1,466	969	47,367
Amortization of organization costs	-	-	42,165
Derivative liability fair value adjustment	(198,251)	-	(2,915,251)
Changes in assets and liabilities:			
Increase in prepaid expenses	(13,232)	(249,500)	(338,684)
Increase in interest receivable	-	-	-
(Decrease) increase in accounts payable and accrued expenses	(45,236)	(394,425)	80,041
Net cash used in operating activities	$ (1,261,292)	$ (1,917,070)	$ (37,204,641)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$ (8,313)	$ (8,740)	$ (69,252)
Purchase of short-term investments	(205,454)	-	(37,576,196)
Purchase of common stock	(46,200)	-	(46,200)
Proceeds from maturities of short-term investments	9,878,700	1,867,330	37,370,742
Organization costs	-	-	(42,165)
Net cash provided by (used in) investing activities	$ 9,618,733	$ 1,858,590	$ (363,071)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$ -	$ 1,343,004	$ 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	$	-	$	1, 343,004	$	53,812,090
Increase (decrease) in cash and cash equivalents		8,357,441		(1,284,524)		16,244,378
Cash and cash equivalents at beginning of period		7,886,937		6,289,723		-
Cash and cash equivalents at end of period	$	16,244,378	$	7,574,247	$	16,244,378
Supplemental cash flow information:						
Cash paid for interest		-		-	$	171,473
Supplemental non-cash activities:						
Cashless exercise of stock options		-		-	$	542,166
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.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. (the “Company”) is a development stage company which was founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing and removing high dose chemotherapy agents to a diseased organ system, while greatly inhibiting their entry into the general circulation system. It is hoped that the procedure will result in a meaningful treatment for cancer. In November 1989, the Company was granted an Investigational Device Exemption (“IDE”) and an Investigational New Drug (“IND”) status for its product by the Food and Drug Administration (“FDA”). The Company is seeking to complete clinical trials in order to obtain separate FDA pre-market approvals for the use of its delivery system using melphalan, a chemotherapeutic agent, to treat malignant melanoma that has spread to the liver.

Note 2: Basis of Financial Statement Presentation

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America (“GAAP”). Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended March 31, 2008 and 2007, and cumulative from inception (August 5, 1988) to March 31, 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: 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 the Company’s general and administrative operating expenses.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

Note 4: 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. The investment is classified as an available for sale security and had a fair value on March 31, 2008 of $37,100, which included a gross unrealized loss of $9,100, which is included as a component of comprehensive loss (Note 5).

Note 5: Stockholders' Equity

During the three months ended March 31, 2008, there were various items that impacted 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

(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 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 vest 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.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to warrants (see below). The warrants are exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the 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 which are subject to mark-to-market adjustment in each period. As a result, for the three month period ended March 31, 2008, the Company recorded pre-tax derivative instrument income of $198,251. The resulting derivative instrument liability totaled $1,353,749 at March 31, 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 2.48%, volatility of 70.91% and an expected life equal to the September 24, 2012 contractual life of the warrants.

The following table sets forth changes in stockholders’ equity during the three months ended March 31, 2008:

Table of Stockholders' Equity

	Common Stock $0.01 Par Value Issued and Outstanding No. of Shares	Amount	Additional Paid in Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage	Total	Comprehensive loss
Balance at December 31, 2007	25,287,384	$ 252,593	$ 56,626,533	-	$ (40,450,278	$ 16,428,848	
Compensation expense for issuance of stock options			51,707			51,707	
Components of comprehensive loss:							
Change in unrealized loss on investments				$ (9,100		(9,100)	$ (9,100
Net loss for three months ended					(1,057,746)	(1,057,746)	$ (1,057,746

March 31, 2008														
Total comprehensive loss													$	(1,066,846
Balance at March 31, 2008	25,287,384	$	252,593	$	56,678,240	$	(9,100	$	(41,508,024	$	15,413,709			

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

Note 6: Stock Option Plan

The Company has adopted the provisions of Statement of Financial Accounting Standards No. 123R, "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 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 2000 and 2001 Stock Option Plans and 2004 Stock Incentive Plan became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. Stock option activity for the three-month period ended March 31, 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	$	$ 4.54	3.96

			1.88 - $7.14			
Granted	50,000		1.74		1.74	
Expired	-		-		-	
Exercised	-		-		-	
Outstanding at March 31, 2008	1,190,000	$	1.74 - $7.14	$	4.42	3.76

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

Note 7: Assets and Liabilities Measured at Fair Value

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.

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

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.

Restricted Stock

Currently, the Company owns 100,000 shares of restricted common stock of AEMD. The valuation of such stock is determined utilizing the current quoted market price of AEMD which is then discounted to reflect the lack of marketability of the stock held due to the selling restrictions. 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.

Money Market Funds and Treasury Bills

Cash and cash equivalents includes a money market account valued at $16,223,868. The Company also has a U.S. treasury bill totaling $205,454.

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

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 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 March 31, 2008

	Level 1	Level 2	Level 3	Balance at March 31, 2008
Assets				
Restricted stock	$ —	$ 37,100	$ —	$ 37,100
Money Market Funds	$ 16,223,868	$ —	$ —	$ 16,223,868
Treasury bills	$ 205,454	$ —	$ —	$ 205,454
Liabilities				
Derivative financial instruments	$ —	$ 1,353,749	$ —	$ 1,353,749

The Company does not have any fair value measurements using significant unobservable inputs (Level 3) as of March 31, 2008.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)
Notes to Condensed Financial Statements

Note 8: Income Taxes

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 likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the consolidated 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.

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

FORWARD LOOKING STATEMENTS

Certain statements in this Form 10-Q, including statements of our and management's expectations, intentions, plans, objectives and beliefs, including those contained in or implied by "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that is subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expansion and possible results from expansion, our expected growth, our capital budget and future capital requirements, the availability of funds and our ability to meet future capital needs, the realization of our deferred tax assets, and the assumptions described in this report underlying such forward-looking statements. Actual results and developments could differ materially from those expressed in or implied by such statements due to a number of factors, including without limitation, those described in the context of such forward-looking statements, our expansion strategy, our ability to achieve operating efficiencies, industry pricing and technology trends, evolving industry standards, domestic and international regulatory matters, general economic and business conditions, the strength and financial resources of our competitors, our ability to find and retain skilled personnel, the political and economic climate in which we conduct operations, the risks discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission (the "SEC") on March 12, 2008 (the "2007 Form 10-K"), under Item 1, "Description of Business," and other risk factors described from time to time in our other documents and reports filed with the SEC. We do not assume any responsibility to publicly update any of our forward-looking statements regardless of whether factors change as a result of new information, future events or for any other reason. We advise you to review any additional disclosures we make in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Reports on Form 10-K filed with the SEC.

Overview

Since our founding in 1988 by a team of physicians, we have been a development stage company engaged primarily in developing and testing the Delcath system for the treatment of liver cancer. A substantial portion of our historical expenses have been for the development of our medical device and the clinical trials of our product, and the pursuit of patents worldwide, as described in our 2007 Form 10-K under Item 1, "Patents, Trade Secrets and Proprietary Rights." We expect to continue to incur significant losses from costs for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishment of a sales and marketing organization without any significant revenues. A detailed description of the cash used to fund historical operations is in the financial statements and the notes thereto included in this report. Without an FDA-approved product and commercial sales, we will continue to be dependent upon existing cash and the sale of equity or debt to fund future activities. While the amount of future net losses and time required to reach profitability are uncertain, our ability to generate significant revenue and become profitable will depend on our success in commercializing our device.

During 2001, Delcath initiated the clinical trial of the system for isolated liver perfusion using the chemotherapeutic agent, Melphalan. Enrollment of new patients in the Phase I trial was completed in 2003.

In 2004, we commenced a Phase II clinical trial protocol for the study of the Delcath drug delivery system for inoperable primary liver cancer and adenocarcinomas and neuroendocrine cancers that have metastasized to the liver using Melphalan.

In 2006, we started enrolling and treating patients in a Phase III protocol for the study of the Delcath drug delivery system for inoperable melanoma in the liver using Melphalan under the Fast Track and SPA approved protocol.

In April 2008, the Institutional Review Board of the University of Maryland Medical Center approved its participation in the Phase III study. The Phase III study is being led by the National Cancer Institute which previously approved the study's expansion to a multi-center trial. Delcath and the University of Maryland Medical Center have entered into a clinical research agreement enabling the hospital to immediately begin recruiting and treating patients.

Over the next 12 months, we expect to continue to incur substantial expenses related to the research and development of our technology, including Phase III and Phase II clinical trials using melphalan with the Delcath System. Additional funds, when available, will be committed to pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath System for the treatment of liver cancer, and the development of additional products and components. We will also continue efforts to qualify additional sources of the key components of our device, in an effort to further reduce manufacturing costs and minimize dependency on a single source of supply.

Results of Operations for the Three Months Ended March 31, 2008

We have operated at a loss for our entire history. We had a net loss for the three months ended March 31, 2008, of $1,057,746, which is $216,368 less than the net loss from continuing operations for the same period in 2007. This decreased loss is primarily due to the adjustment to the derivative instrument expense as part of the calculation of the fair value of warrants issued in September 2007 as explained above in Note 5 - Stockholders' Equity - to the financial statements..

General and administrative expenses decreased from $500,819 during the three months ended March 31, 2007, to $441,004 for the three months ended March 31, 2008, or $59,815, a 12% change. This decrease is primarily attributed to the reduced accounting fees this year, as this is the second year of our status as an accelerated filer, and the higher legal fees paid last year as part of the final resolution of various legal matters.

During the first quarter of 2008, we incurred $988,956 in research and development costs, as compared to $888,951 during the first quarter of 2007, an increase of $100,005, or 11.2%. This increase is primarily due to expenses relating to exploring new and improved filter technology to remove current and future therapeutic agents that can be used with the Delcath PHP System.

Interest income shown is from our money market and Treasury bill and note investments. During the three months ended March 31, 2008, the Company had interest income of $173,963, as compared to interest income of $115,656, or a 50.4% change, for the same period in 2007. This increase is due to the investment of the net proceeds from the sale of our common stock and warrants that was received during the third quarter of fiscal 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 there can be no assurance that we will ever achieve consistent profitability. We are not projecting any capital expenditures that will significantly affect our liquidity during the next 12 months. However, our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including clinical studies; 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. In addition, we intend to hire at least one additional employee.

At March 31, 2008, we had cash and cash equivalents of $16,244,378, as compared to $7,886,937 at December 31, 2007 and $7,574,247 at March 31, 2007. Nearly all of our funds are currently invested in money market accounts which are shown in our financial statements as part of “Cash and Cash Equivalents.” In the year ended December 31, 2007, our invested funds were nearly equally divided between money market accounts and Treasury bills and notes.

During the three months ended March 31, 2008, we used $1,261,292 of cash in our operating activities. This amount compares to $1,917,070 used in our operating activities during the comparable three-month period in 2007. This decrease of $655,778, or 34.2%, is primarily due to payments in 2007 to NCI as part of our newly extended CRADA agreement, and final payments in 2007 to various parties as part of the settlements of the lawsuits that had commenced in 2006.

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. Please see the detailed discussion of our various sales of securities described in Note 2 to our 2007 Form 10-K. In addition, we received proceeds of approximately $5.6 million from private placements we completed in 2004, approximately $2.2 on exercise of warrants and options in 2004, approximately $2.5 million from a private placement we completed in 2005, approximately $5.5 million on exercise of warrants and options in 2005; approximately $5.1 million on exercise of warrants and options in 2006; approximately $1.3 million on exercise of warrants and options in 2007, and approximately $13.3 million from a private placement we completed in 2007.

Application of Critical Accounting Policies.

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 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.

The Company has adopted the provisions of Statement of Financial Accounting Standards No. 123R, “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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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 value of these 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. The investment is classified as an available for sale security and had a fair value on March 31, 2008 of $37,100, which included a gross unrealized loss of $9,100, which is included as a component of comprehensive loss (Note 5).

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 three month period ended March 31, 2008, the Company recorded pre-tax derivative instrument income of $198,251. The resulting derivative instrument liability totaled $1,353,749 at March 31, 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 2.48%, volatility of 70.91% and an expected life equal to the September 24, 2012 contractual life of the warrants.

Item 4. Controls and Procedures

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.

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 has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II:
OTHER INFORMATION

Item 1. Legal Proceedings

We have been involved in a legal proceeding that was originally filed on August 12, 2005 in the United States District Court, District of Connecticut against Elizabeth L. Enney (the “Defendant”). The named plaintiffs are Delcath Systems, Inc. and M.S. Koly (former CEO, President, Treasurer and Director of Delcath), individually and as a Director of Delcath Systems, Inc. (collectively, the “Plaintiffs”). The operative complaint seeks damages for libel. In May 2006, the libel claims were dismissed for lack of personal jurisdiction, and in July 2006, Plaintiffs filed a new libel claim in the United States District Court for the Northern District of Georgia. On November 1, 2006, Defendant filed a Motion for Judgment claiming that Plaintiffs’ complaint and the attachments thereto, on their face, were insufficient to support Plaintiffs’ libel claim as a matter of law. On December 22, 2006, Defendant filed a motion under Rule 11 of the Federal Rules of Civil Procedure seeking an order directing payment to the Defendant of reasonable attorneys’ fees and expenses by Plaintiff. On April 19, 2007, the entire action was ordered and adjudged to be dismissed, and the Defendant was granted recovery of her costs, however, her motion for sanctions against the Plaintiffs was denied.

On May 21, 2007, Defendant filed an appeal to the United States Court of Appeals for the 11th Circuit from the final judgment and order of the court entered on April 19, 2007 denying Defendant’s motion for sanctions against the Plaintiffs. On March 7, 2008, the Court of Appeals found that the District Court abused its discretion by denying the Defendant’s motion for sanctions, and reversed the District Court’s order and remanded it to the District Court for further proceedings to determine the appropriate amount of the sanctions. The Defendant has quantified the costs she claims were occasioned by this lawsuit in a separate action (in which we are not a party) at $450,000, an amount we would dispute vigorously if the Defendant were to claim that amount in the remanded proceedings in the District Court. However, no assurance can be given concerning the amount of the sanctions for which we may ultimately be held liable.

Item 1A. Risk Factors

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.

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

None.

Item 3. Defaults upon Senior Securities

None.

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

None.

Item 5. Other Information

There were no matters required to be disclosed in a Current Report on Form 8-K during the fiscal quarter covered by this report that were not so disclosed.

There were no changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors since the Company last disclosed such procedures in our proxy statement filed in connection with our Annual Meeting of Stockholders to be held on June 4, 2008.

Item 6. Exhibits

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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 9, 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)