DELCATH SYSTEMS INC
Form 10QSB
May 16, 2005

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

[x] Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2005

[ ] Transition report under 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 Small Business Issuer as Specified in Its Charter)

Delaware	06-1245881
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1100 Summer Street, 3rd Floor, Stamford, CT 06905

(Address of Principal Executive Offices)

(203) 323-8668

(Issuer's Telephone Number, Including Area Code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 [ ]

As of May 13, 2005, 15,483,445 shares of the Issuer's common stock, $0.01 par value, issued and outstanding.

Transitional Small Business Disclosure Format (check one): Yes _____ No __X__

Index

Delcath Systems, Inc.
(A Development Stage Company)
Balance Sheet
(Unaudited)
March 31, 2005

Assets	March 31, 2005
Current assets:	
Cash and cash equivalents	$ 1,617,687
Certificate of deposit	5,047,077
Interest receivable	42,088
Prepaid insurance	64,330
Total current assets	6,771,182
Furniture and fixtures, net	12,092
Total assets	$ 6,783,274

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 622,227
Total current liabilities	622,227
Stockholders' equity	
Common stock, $.01 par value, 70,000,000 shares authorized	154,834
Additional paid-in capital	29,892,088
Deficit accumulated during development stage	(23,885,875)
Total stockholders' equity	6,161,047
Total liabilities and stockholders' equity	$ 6,783,274

See accompanying notes to condensed financial statements

Delcath Systems, Inc.
(A Development Stage Company)
Statements of Operations
(Unaudited)

	Three Months Ended March 31,		Cumu From I (August t
	2005	2004	March
Costs and expenses:			
General and administrative expenses	$ 415,258	$ 228,644	$ 7,4
Research and development costs	551,361	487,840	15,8
Total costs and expenses	966,619	716,484	23,3
Operating loss	(966,619)	(716,484)	(23,

Interest income	51,292	6,950	1,
Interest expense	-	-	(
Net loss	$ (915,327)	$ (709,534)	$ (22,
Common share data:			
Basic and diluted loss per share	$ (0.06)	$ (0.07)	
Weighted average number of shares of common stock outstanding	15,358,028	9,805,626	

See accompanying notes to condensed financial statements

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004	Cumulative from inception (August 5, 1988) to March 31, 2005
Cash flows from operating activities:			
Net loss	$ (915,327)	$ (709,534)	$ (22,387,270)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock option compensation expense	-	-	2,525,392
Stock and warrant compensation expense issued for consulting services	-	-	236,286
Depreciation expense	1,515	1,248	33,207
Amortization of organization costs	-	-	42,165
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	(16,514)	15,000	(64,330)
(Increase) interest receivable	(9,202)	(1,099)	(42,087)
Increase in accounts payable and accrued expenses	57,602	81,538	622,227
Net cash used in operating activities	(881,927)	(612,847)	(19,034,409)

Cash flows from investing activities:			
Purchase of furniture and fixtures	-	-	(45,300)
Purchase of short-term investments	(1,047,077)	-	(12,016,781)
Proceeds from maturities of short-term investments	3,055,129	1,014,575	6,969,704
Organization costs	-	-	(42,165)
Net cash provided by (used in) investing activities	2,008,052	1,014,575	(5,134,542)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	289,227	2,949,201	24,632,312
Repurchases of outstanding common stock	-	-	(51,103)
Dividends paid	-	-	(499,535)
Proceeds from short-term borrowings	-	-	1,704,964
Net cash provided by financing activities	289,227	2,949,201	25,786,638
Increase (decrease) in cash and cash equivalents	1,415,352	3,350,929	1,617,687
Cash and cash equivalents at beginning of period	202,335	313,615	-
Cash and cash equivalents at end of period	$ 1,617,687	$ 3,664,544	$ 1,617,687
Cash paid for interest	$ -	$ -	$ 171,473
Supplemental disclosure of non-cash activities:			
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

See accompanying notes to condensed financial statements

(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 IDE (Investigational Device Exemption) and an IND (Investigational New Drug) for its product by the FDA (Food and Drug Administration). 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 doxorubicin and melphalan, chemotherapeutic agents, to treat malignant melanoma that has spread to the liver.

Note 2: Basis of Presentation

The accompanying financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America. 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, 2005 and 2004 and cumulative from inception (August 5, 1988) to March 31, 2005.

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, 2004, which are contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed with the Securities and Exchange Commission.

Note 3: 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.

Note 4: Stockholders' Equity

During the three months ended March 31, 2005, the Company received net proceeds of $32,377 ($1.022 per share) upon the exercise of 6,336 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the 2003 public offering. This resulted in the issuance of 31,680 shares of common stock together with a similar amount of Representative's Common Stock Warrants. In addition, 146,680 Representative's Common Stock Warrants were exercised ($1.28 per share) with a similar amount of common stock being issued and receipt of net proceeds of $188,751.

The Company received a net amount of $68,100 upon the exercise of 90,000 in stock options during the quarter. 60,000 options were exercised at a price of $0.71 per share and 30,000 were exercised at a price of $0.85 per share.

The following table sets forth changes in stockholders' equity during the three months ended March 31, 2005:

	Common Stock, $0.01 Par Value Issued and Outstanding		Additional	Defici
	No. of shares	Amount	Paid in Capital	Deve
Balance at December 31, 2004	15,215,085	$152,151	$29,605,543	$(2
Issuance of common stock in connection with the exercise of 2003 Representative's Unit Warrants	31,680	317	32,060	
Issuance of common stock in connection with the exercise of Representative's Common Stock Warrants	146,680	1,466	187,285	
Issuance of common stock in connection with the exercise of stock options	90,000	900	67,200	
Net loss for three months ended March 31, 2005				
Balance at March 31, 2005	15,483,445	$154,834	$29,892,088	$(2

Note 5: Stock Option Plan

The Company has historically accounted for its employee stock option plans in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation expense is recorded on the date of grant only if the current fair market value of the underlying stock exceeds the exercise price.

Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure required by SFAS No. 123.

Following the methodology of SFAS No. 123 regarding compensation costs based on the fair value for all employee stock option grants, the net loss and net loss per share for the three months ended March 31, 2005 and 2004 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended March 31,	
	2005	2004
Net loss, as reported	$ (915,327)	$ (709,534)
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(17,618)	(25,392)
Pro forma net loss	(932,945)	(734,926)
Loss per share (basic and diluted):		
As reported	$ (0.06)	$ (0.07)
Pro forma	(0.06)	(0.07)

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), "Share-based Payment" that will require the Company to expense costs related to share-based payment transaction with employees. With limited exceptions, SFAS No. 123(R) requires that the fair value of share-based payments to employees be expensed over the period service is received and eliminates the ability to account for these instruments under the intrinsic value method prescribed by APB No. 25, and allowed under the original provisions of SFAS No. 123. SFAS No. 123(R) becomes mandatorily effective for the Company on January 1, 2006. SFAS No. 123(R) allows for either prospective recognition of compensation expense or retrospective recognition, which may be back to the original issuance of SFAS No. 123 or only to interim periods in the year of adoption. The Company is currently evaluating these transition methods.

SFAS No. 123(R) allows the use of both closed form models (e.g., Black-Scholes Model) and open form models (e.g., lattice models) to measure the fair value of the share-based payment as long as that model is capable of incorporating all of the substantive characteristics unique to share-based awards. In accordance with the transition provisions of SFAS No. 123(R), the expense attributable to an award will be measured in accordance with the Company's measurement model at that award's date of grant.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

(a) Plan of Operation

FORWARD LOOKING STATEMENTS

This report contains forward-looking statements which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to our ability to successfully complete Phase III clinical trials and secure regulatory approval of our current or future drug-delivery system and uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

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. 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. 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. The Phase I trial at the National Cancer Institute marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapeutic agent used in our initial clinical trials. Enrollment of new patients in the Phase I trial was completed in 2003 and following the 2004 presentation and adoption of a Phase II clinical trial protocol, patients are being enrolled and treated.

During 2004, we commenced a Phase III clinical trial in Australia to proceed with study of the Delcath drug delivery system for inoperable cancer in the liver using doxorubicin. We are currently in discussions with additional sites worldwide to expand this trial.

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 clinical trials using doxorubicin with the Delcath system 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.

Liquidity and Capital Resources

Our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures at least through the end of 2006. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. The Company is projecting the hiring of one additional employee.

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.

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance of its ever achieving consistent profitability. The Company believes its capital resources are adequate to fund operations for at least the next twelve months but anticipates that it will require additional working capital after 2006. There can be no assurance that such working capital will be available on acceptable terms, if at all.

During the three months ended March 31, 2005, the Company had exercises of previously issued warrants together with exercises of stock options. Please see Note 4 to the March 31, 2005 Condensed Financial Statements included in Part I of this filing and incorporated herein by reference for a complete description of share issuances together with receipt of proceeds. We plan to use the net proceeds to fund, in part, the Phase III clinical trial using doxorubicin and the Phase II clinical trial at NCI using melphalan.

Application of Critical Accounting Policies

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's financial statements contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed with the Securities and Exchange Commission. The Company has not adopted any significant new accounting policies or modified the application of existing policies during the three months ended March 31, 2005.

(b) Management's Discussion and Analysis of Financial Condition and Results of Operations

Not Applicable.

(c) Off-balance sheet arrangements

The Company does not have any off-balance sheet arrangements.

Item 3. CONTROLS AND PROCEDURES

Based on an evaluation of the Company's disclosure controls and procedures performed by the Company's Chief Executive Officer and its Chief Financial Officer as of the end of the period covered by this report, the Company's Chief Executive Officer and its 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 is recorded, processed, summarized and reported within the time periods specified in the rules and forms issued by the Securities and Exchange Commission. 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 Securities 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.

Since the date of the evaluation described above, there were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

PART II
OTHER INFORMATION

Item 6. EXHIBITS

31.1 Certification by Chief Executive Officer Pursuant to Rule 13a-14.

31.2 Certification by Chief Financial Officer Pursuant to Rule 13a-14.

11.

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.

12.

SIGNATURES

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

DELCATH SYSTEMS, INC.
(Registrant)

May 16, 2005

/s/ PAUL M. FEINSTEIN

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

13.

EXHIBIT INDEX

Number	Description
31.1	Certification by Chief Executive Officer Pursuant to Rule 13a-14.
31.2	Certification by Chief Financial Officer Pursuant to Rule 13a-14.
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.