DELCATH SYSTEMS INC
Form 10QSB
August 11, 2005

UNITED STATES

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 June 30, 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 August 8, 2005, 16,573,965 shares of the Issuer's common stock, $0.01 par value, were issued and outstanding.

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

DELCATH SYSTEMS, INC.

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Delcath Systems, Inc.
(A Development Stage Company)
Balance Sheet
(Unaudited)
June 30, 2005

Assets	June 30, 2005
Current assets:	
Cash and cash equivalents	$ 830,597
Certificate of deposit	5,047,077
Interest receivable	82,934
Prepaid insurance	19,278
Total current assets	5,979,884

Furniture and fixtures, net		10,576
Total assets	$	5,990,462
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$	430,328
Total current liabilities		430,328
Stockholders' equity		
Common stock, $0.01 par value, 70,000,000 shares authorized		155,044
Additional paid-in capital		29,916,049
Deficit accumulated during development stage		(24,510,959)
Total stockholders' equity		5,560,134
Total liabilities and stockholders' equity	$	5,990,462

See accompanying notes to condensed financial statements

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

	Three Months Ended June 30, 2005	Three Months Ended June 30, 2004	Six Months Ende June 30, 2005	Six Months Ende June 30, 20
Costs and expenses:				
General and administrative expenses	$ 292,145	$ 278,644	$ 707,403	$ 5
Research and development costs	382,806	584,334	934,167	1,0
Total costs and expenses	674,951	862,978	1,641,570	1,5

Operating loss	(674,951)	(862,978)	(1,641,570)	(1,5
Other income (expense):				
Interest income	49,867	36,353	101,159	
Interest expense	-	-	-	
Net loss	$ (625,084)	$ (826,625)	$ (1,540,411)	$ (1,5
Common share data:				
Basic and diluted loss per share	$ (0.04)	$ (0.07)	$ (0.10)	$
Weighted average number of shares of common stock outstanding	15,491,060	11,520,573	15,424,912	10,66

See accompanying notes to condensed financial statements

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30, 2005	Six Months Ended June 30, 2004
Cash flows from operating activities:		
Net loss	$ (1,540,411)	$ (1,536,159)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock option compensation expense	-	-
Stock and warrant compensation expense issued for consulting services	-	-
Depreciation expense	3,030	2,496
Amortization of organization costs	-	-
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses	28,538	6,434
(Increase) in interest receivable	(50,048)	(11,380)

(Decrease) increase in accounts payable and accrued expenses	(134,298)	264,200
Net cash used in operating activities	(1,693,188)	(1,274,409)
Cash flows from investing activities:		
Purchase of furniture and fixtures	-	-
Purchase of short-term investments	(1,047,077)	(2,000,000)
Proceeds from maturities of short-term investments	3,055,129	1,014,575
Organization costs	-	-
Net cash provided by (used in) investing activities	2,008,052	(985,425)
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	313,398	3,617,852
Repurchases of outstanding common stock	-	-
Dividends paid	-	-
Proceeds from short-term borrowings	-	-
Net cash provided by financing activities	313,398	3,617,852
Increase in cash and cash equivalents	628,262	1,358,018
Cash and cash equivalents at beginning of period	202,335	313,615
Cash and cash equivalents at end of period	$ 830,597	$ 1,671,633
Cash paid for interest	$ -	$ -
Supplemental disclosure of non-cash activities:		
Conversion of debt to common stock	$ -	$ -
Common stock issued for preferred stock dividends	$ -	$ -
Conversion of preferred stock to common stock	$ -	$ -
Common stock issued as compensation for stock sale	$ -	$ -

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 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 June 30, 2005 and 2004 and cumulative from inception (August 5, 1988) to June 30, 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 six months ended June 30, 2005, the Company received net proceeds of $43,108 ($1.022 per share) upon the exercise of 8,436 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the 2003 public offering. This resulted in the issuance of 42,180 shares of common stock together with a similar amount of Representative's Common Stock Warrants. In addition, 157,180 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 $202,191.

The Company received a net amount of $68,100 upon the exercise of 90,000 in stock options during the six months ended June 30, 2005. 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 six months ended June 30, 2005:

	Common Stock, $0.01 Par Value Issued and Outstanding		Additional	Deficit Du
	No. of shares	Amount	Paid in Capital	Develo
Balance at December 31, 2004	15,215,085	$152,151	$29,605,543	$(22
Issuance of common stock in connection with the exercise of 2003 Representative's Unit Warrants	42,180	422	42,686	
Issuance of common stock in connection with the exercise of Representative's Common Stock Warrants	157,180	1,571	200,620	
Issuance of common stock in connection with the exercise of stock options	90,000	900	67,200	
Net loss for six months ended June 30, 2005	-	-	-	(1
Balance at June 30, 2005	15,504,445	$155,044	$29,916,049	$(24

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 and six months ended June 30, 2005 and 2004 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (625,084)	$ (826,625)	$(1,540,411)	$ (1,536,159)
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0	0	0
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(17,618)	(25,392)	(35,235)	(50,783)
Pro forma net loss	(642,702)	(852,017)	(1,575,646)	(1,586,942)
Loss per share (basic and diluted):				
As reported	$ (0.04)	$ (0.07)	$ (0.10)	$ (0.14)
Pro forma	(0.04)	(0.07)	(0.10)	(0.15)

In December 2004, the FASB issued SFAS No. 123 (Revised 2004)("SFAS No. 123(R)") "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. A 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 for three types of cancer in the liver, patients are being enrolled and treated. This study involves patients with primary liver cancer, neuroendocrine tumors and metastatic adenocarcinomas in the liver, including liver metastasis from colorectal cancer.

In May 2005, Delcath announced that it received "fast-track" status from the FDA for treating metastatic melanoma in the liver with melphalan. The FDA's fast-track program is designed to facilitate development and expedite the review of new drugs or, in the case of Delcath, a new drug-device combination, having the potential to treat illnesses which currently lack adequate therapy.

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 for 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 two additional employees.

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 six months ended June 30, 2005, the Company had exercises of previously issued warrants together with exercises of stock options. Please see Note 4 to the June 30, 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 six months ended June 30, 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 2. UNREGISTERED SALES OF EQUITY SECURITIES

On August 4 and August 5, 2005, the Company sold an aggregate of 1,069,520 shares of its Common Stock upon exercise of all of its then outstanding Series B Warrants to Purchase Shares of Common Stock dated November 24, 2004 (the "Series B Warrants"). Based on the exercise price of $2.60 for each of the Series B Warrants, the Company received an aggregate of $2,780,752 upon such exercises. The Company claims an exemption from registration of the offer and sale of the shares of Common Stock issued upon exercise of the Series B Warrants under Rule 506 under the Securities Act of 1933 on the basis that each of the purchasers is an accredited investor. The resale of these shares is covered by an effective Registration Statement under the Securities Act of 1933.

No underwriter was involved in the exercise of the Series B Warrants, and the Company paid no underwriting discount or commission in connection therewith.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 14, 2005, the Company held its 2005 Annual Meeting of Stockholders. At the meeting, the stockholders voted on the election of two Class II directors of the Company to hold office until the Annual Meeting of Stockholders in 2008 and until their successors are duly elected and qualified.

The stockholders voted 12,652,834 shares in favor of electing M. S. Koly to serve as a Class II director and withheld authority to vote 21,303 shares. The stockholders voted 12,652,998 shares in favor of electing Samuel Herschkowitz, M.D. to serve as a Class II director and withheld authority to vote 21,139 shares. The term of office of each of Mark A. Corigliano and Victor Nevins as Class III directors will continue until the Annual Meeting of Stockholders in 2006. The term of office of Daniel Isdaner as a Class I director will continue until the Annual Meeting of Stockholders in 2007.

Item 6. EXHIBITS

3(i). Certificate of Incorporation, as amended to June 30, 2005.

4. Warrant Agreement dated as of July 22, 2005 between the Company and American Stock Transfer & Trust Company, as warrant agent, together with the form of 2005 Redeemable Common Stock Purchase Warrants - Series A.

10.1 Employment Agreement between the Company and M. S. Koly, as amended by Amendment No. 1 thereto.

10.2 Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan.

10.3 Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan.

10.4 Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan.

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.

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)

August 11, 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)

EXHIBIT INDEX

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