DELCATH SYSTEMS INC
Form 10QSB
May 17, 2004

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, 2004

[ ] 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)

As of April 15, 2004, there were 11,498,626 shares of the Issuer's common stock, $0.01 par value, 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)
March 31, 2004

Assets	March 31, 2004
Current assets:	
Cash and cash equivalents	$ 3,949,544
Certificate of deposit	1,017,321
Interest receivable	796
Prepaid insurance	32,500
Total current assets	5,000,161
Furniture and fixtures, net	12,539
Due from affiliate	24,000
Total assets	$ 5,036,700

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 389,238
Deposit regarding sale of shares	285,000
Total current liabilities	674,238
Stockholders' equity	
Common stock	112,230
Additional paid-in capital	24,663,982
Deficit accumulated during development stage	(20,413,750)
Total stockholders' equity	4,362,462
Total liabilities and stockholders' equity	$ 5,036,700

See accompanying notes to condensed financial statements

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

	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003	Cumulative From Inception (August 5, 1988 to March 31, 2004
Costs and expenses:			
General and administrative expenses	$ 228,644	$ 237,433	$ 6,239,690
Research and development costs	487,840	300,829	13,497,336
Total costs and expenses	716,484	538,262	19,737,026
Operating loss	(716,484)	(538,262)	(19,737,026)
Interest income	6,950	7,621	993,354
Interest expense	-	-	(171,473)

Net loss	$ (709,534	$ (530,641)	$ (18,915,145)
Common share data:			
Basic and diluted loss per share	$ (0.07)	$ (0.13)	
Weighted average number of shares of common stock outstanding	9,805,626	4,118,897	

See accompanying notes to condensed financial statements

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

(Unaudited)

	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003	Cumulative from inception (August 5, 1988) to March 31, 2004
Cash flows from operating activities:			
Net loss	$ (709,534)	$ (530,641)	$ (18,915,145)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock option compensation expense	-	-	2,520,170
Stock and warrant compensation expense issued for consulting services	-	-	236,286
Depreciation expense	1,248	1,248	27,414
Amortization of organization costs	-	-	42,165
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	15,000	30,500	(32,500)
(Increase) decrease in interest receivable	(1,099)	5,406	(15,371)
Due from affiliate	-	-	(24,000)
Increase in accounts payable and accrued expenses	81,538	123,882	341,738
Net cash used in operating activities	(612,847)	(369,605)	(15,819,243)
Cash flows from investing activities:			
Purchase of furniture and fixtures	-	(5,029)	(39,953)
Purchase of short-term investments	-	-	(4,917,321)
Proceeds from maturities of short-term investments	1,014,575	370,000	3,914,575

Organization costs	-	-	(42,165)
Net cash provided by (used in) investing activities	1,014,575	364,971	(1,084,864)
Cash flows from financing activities:			
Deferred costs in connection with a proposed financing transaction	-	(118,751)	-
Deposit regarding sale of shares	285,000	-	285,000
Net proceeds from sale of stock and exercise of stock options and warrants	2,949,201	-	19,129,325
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	3,234,201	(118,751)	20,853,651
Increase (decrease) in cash and cash equivalents	3,635,929	(123,385)	3,949,544
Cash and cash equivalents at beginning of period	313,615	1,063,650	-
Cash and cash equivalents at end of period	$ 3,949,544	$ 940,265	$ 3,949,544
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 dividend	$ -	$ -	$ 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

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 status (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 inoperable tumors in 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, 2004 and 2003 and cumulative from inception (August 5, 1988) to March 31, 2004.

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, 2003, which are contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2003 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: Sale of Common Stock and Warrants

On May 20, 2003, the Company completed the sale of 677,419 units of its securities at a selling price of $3.10 per unit. Each unit consisted of five shares of common stock and five warrants (the "2003 Warrants") each to purchase one share of common stock. The 2003 Warrants are exercisable at $0.775, and they expire on May 20, 2008. A total of 3,387,095 shares of common stock and 2003 Warrants each were issued, and the Company received gross proceeds of $2,099,999. In addition, the Company granted the underwriters an option to purchase up to an aggregate of an additional 15% of the total units sold in the public offering. On June 10, 2003 the underwriters exercised their option for the full allotment of additional units, and the Company issued 508,060 shares of its common stock and 508,060 of its 2003 Warrants, and received gross proceeds of $314,997. The Company received $68 for granting the underwriters an option to purchase until May 14, 2008, 67,741 units at 165% of the offering price. As a result of the foregoing, the Company received total proceeds of $2,415,064 ($1,517,666 after underwriting fees and other expenses).

During the quarter ended March 31, 2004, the Company received net proceeds of $229,106 as 261,105 of the 2003 Warrants were exercised along with the 20,265 warrants the Company issued in a private placement in 2002. From issuance through March 31, 2004, the Company has received $1,493,556 of net proceeds from the exercise of 2003 Warrants for which it has issued 1,991,685 shares of its common stock.

In March 2004 the Company completed the sale of 1,197,032 shares of its common stock and the issuance of warrants to purchase 299,258 common shares at $3.01 per share in a private placement to institutional and accredited investors. The Company received net proceeds (after estimated accrued registration costs of approximately $47,500) of $2,672,595 in this transaction, and has agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securites Act of 1933.

The following table sets forth changes in stockholders' equity during the three months ended March 31, 2004:

	Common Stock, $.01 Par Value Outstanding		Additional	Deficit During
	No. of shares	Amount	Paid in Capital	Develop
Balance at December 31, 2003	9,744,632	$97,446	$21,777,065	$(19
Sale of common stock and warrants in March 2004, net of related costs	1,197,032	11,970	2,660,625	
Exercise of 2002 Warrants	20,265	203	26,547	
Exercise of 2003 Warrants	261,105	2,611	199,745	
Net loss for three months ended March 31, 2004				(
Balance at March 31, 2004	11,223,034	$112,230	$24,663,982	$(20,

The Company completed an additional private placement of 290,257 shares of Common Stock and an aggregate of 74,814 warrants to purchase shares of its common stock in early April 2004, under the same terms and conditions as those sold in March 2004. In this connection, a deposit of $285,000 (net of commission) was received for the sale of this common stock and warrants prior to the end of the quarter and is reflected as such on the balance sheet as a liability.

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, 2004 and 2003 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended Mar. 31,	
	2004	2003
Net loss, as reported	$ (709,534)	$ (530,641)
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	(25,392)	(16,978)
Pro forma net loss	$ (734,926)	$ (547,619)
Loss per share (basic and diluted):		
As reported	$ (0.07)	$ (0.13)
Pro forma	(0.07)	(0.13)

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, the clinical trials of our product and the vigorous pursuit of patents worldwide, which now total nine. We expect to continue to incur significant losses from expenditures for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishment of a sales and marketing organization without any significant revenues. 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 the 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.

We have entered into arrangements with the Sydney Melanoma Unit of the University of Sydney, Sydney Cancer Centre to recruit patients for a Phase III study of the Delcath drug delivery system using doxorubicin to treat malignant melanoma that has spread to the liver and these trials have recently been started.

During 2001, we initiated the clinical trial of the system for isolated liver perfusion using the chemotherapy agent, melphalan. The Phase I clinical trial at the National Cancer Institute ("NCI") marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapy agent used in our initial clinical trials. Enrollment of new patients by the NCI in the Phase I trial using melphalan was completed in 2003 and enrolled patients will continue to be followed.

NCI is currently preparing a clinical trial protocol for a Phase II trial using melphalan, based on the data collected in the Phase I study. Enrollment in this Phase II study is expected to begin in during 2004. The Principal Investigator at the NCI has informed the Company that he has presented his findings in appropriate medical forums and is reviewing his data in preparation for a meeting with the FDA to discuss the Phase II protocol.

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 I and II clinical trials using melphalan with the Delcath system. Additional funds, when and if 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.

On April 1, 2004 we received a letter from The Nasdaq Stock Market that noted our failure as of December 31, 2003 to meet any of the alternative criteria for continued listing of our common stock set forth in Marketplace Rule 4310(c)(2)(B) (the "Rule"). As of December 31, 2003, we did not have $2.5 million of stockholders' equity or net income from continuing operations of $500,000 for the year ended December 31, 2003 or for two of the three years ended December 31, 2003. Further, at that date, the market value of our common stock was less than $35 million. On April 7, 2004, we responded to the Nasdaq letter noting our completion of the transactions described in Part II, Item 2 of this Report and the additional private sale in early April of common stock and warrants for which we received gross proceeds of approximately $700,000. Based on our response to Nasdaq, Nasdaq granted us an extension to time to May 17, 2004 to demonstrate compliance with the Rule. Our unaudited balance sheet as of March 31, 2004 included in this Report shows stockholders equity of $4.3 million (which amount does not include the proceeds of the private placements we closed in April). Based on the foregoing, we believe we have regained compliance with the stockholders' equity requirement of the Rule.

Liquidity and Capital Resources

Our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures at least through 2004. 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. We have operated at a loss for our entire history and we may never achieve consistent profitability. We expect to require additional working capital in the future and such working capital may not be available on acceptable terms, if at all. In addition, we may need additional capital in the future to fully implement our business strategy.

In May 2003, we issued 3,387,095 shares of common stock and an equal number of 2003 Warrants upon the closing of an underwritten public offering. In June 2003, we issued an additional 508,060 shares of common stock and an equal number of 2003 Warrants upon exercise in full of the over allotment option we had granted to the underwriters. During 2003, 1,730,580 of the 2003 Warrants were exercised. During the quarter ended March 31, 2004, an additional 261,105 of the 2003 Warrants were exercised along with the 20,265 warrants the Company issued in a private placement in 2002. As a result of the issuances and exercises, we received net proceeds of approximately $3.0 million. 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. We also anticipate using a portion of the net proceeds to hire an additional employee.

During March 2004, the Company completed the sale of approximately 1,200,000 shares of its Common Stock and the issuance of warrants to purchase approximately 300,000 common shares at $3.01 per share in a private placement to institutional and accredited investors. The Company received net proceeds (after estimated accrued registration costs of approximately $48,000) of approximately

$2,700,000 in this transaction, and has agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securites Act of 1933.

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 10KSB for the year ended December 31, 2003 as filed with the Securities and Exchange Commission. The Company has not adopted any significant new accounting policies during the three months ended March 31, 2004.

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

Not Applicable.

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. CHANGES IN SECURITIES AND SMALL BUSNISS ISSUER PURCHASES OF EQUITY SECURITIES

(a) Not applicable

(b) Not applicable

(c) On March 19 and 22, 2004, the Company sold an aggregate of 1,197,032 shares of its Common Stock and an aggregate of 299,258 warrants to purchase shares of its common stock. The sales of these securities were made in transactions exempt from registration under Rule 506 under the Securites Act of 1933, as amended, to purchasers each of whom qualified as an "accredited investor" with the meaning of Rule 501 thereunder. The aggregate offering price for the securities sold was $2,884,847. While the Company did not pay any underwriting discount or commission with respect to these transactions,, it paid cash and issued warrants to purchase 59,851 shares of its common stock to an entity that acted as placement agent.

An additional sale of 290,257 shares of Common Stock and an aggregate of 74,814 warrants to purchase shares of its common stock were sold in early April 2004 on the same terms and conditions as those sold during March 2004. In connection with these transactions, the Company also paid the placement agents fees in the amount of $179,242.

The warrants issued to the purchasers and to the placement agent have an exercise price per share of $3.01, subject to adjustment under certain circumstances and have a term expiring on March 19, 2009. The Company has filed a Registration Statement on Form S-3 covering, among other things, the resale of the shares sold in the offering and of the shares that might be issued upon exercise of the warrants. Commencing one year after the effective date of the registration statement, the Company has the right to redeem all or a portion of the warrants if certain conditions are met, including that the average per share market value of the Company's common stock for the twenty trading days immediately prior to the notice of redemption has been more than $6.02.

(d) Not applicable

(e) Not applicable

Item 6. Exhibits and Reports on Form 8-K

(a) 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.
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.

(b) Reports on Form 8-K.

During the quarter ended March 31, 2004, the Company filed five Current Reports on Form 8-K as follows:

Date of Report	Items Responded To
January 26, 2004	5 and 7
February 24, 2004	5 and 7
March 9, 2004	5 and 7
March 11, 2004	5 and 7
March 19, 2004	5 and 7

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 17, 2004

/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)