DELCATH SYSTEMS INC
Form 10QSB
May 15, 2003

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, 2003

[ ] 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 May 9, 2003, there were 4,118,897 shares of the Issuer's common stock, $.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, 2003

Assets	March 31, 2003
Current assets:	
Cash and cash equivalents	$ 940,265
Prepaid insurance	66,083
Total current assets	1,006,348
Furniture and fixtures, net	17,531
Deferred costs in connection with a proposed financing transaction	357,322
Due from affiliate	24,000
Total assets	$ 1,405,201

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 299,052
Total current liabilities	299,052
Stockholders' equity	
Common stock	41,189
Additional paid-in capital	19,049,406
Deficit accumulated during development stage	(17,984,446)
Total stockholders' equity	1,106,149
Total liabilities and stockholders' equity	$ 1,405,201

See accompanying notes to condensed financial statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)
Statements of Operations
(Unaudited)

	Three Months Ended March 31, 2003	2002
Costs and expenses:		
General and administrative expenses	$ 237,433	$ 296,332
Research and development costs	300,829	302,465
Total costs and expenses	538,262	598,797
Operating loss	(538,262)	(598,797)
Interest income	7,621	23,858
Interest expense	--	--
Net loss	$ (530,641)	$ (574,939)

Common share data:		
Basic and diluted loss per share	$ (0.13)	$ (0.15)
Weighted average number of shares of common stock outstanding	4,118,897	3,903,816

See accompanying notes to condensed financial statements

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31, 2003	2002
Cash flows from operating activities:		
Net loss	$ (530,641)	$ (574,939)
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	1,248	1,734
Amortization of organization costs	--	--
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses	30,500	22,000
Decrease (increase) in interest receivable	5,406	(17,270)
Due from affiliate	--	--
Increase in accounts payable and accrued expenses	123,882	56,728
Net cash used in operating activities	(369,605)	(511,747)
Cash flows from investing activities:		
Purchase of furniture and fixtures	(5,029)	(6,400)
Purchase of short-term investments	--	(1,552,232)
Proceeds from maturities of short-term investments	370,000	--
Organization costs	--	--
Net cash provided by (used in)		

investing activities	364,971	(1,558,632)
Cash flows from financing activities:		
Deferred costs in connection with a proposed financing transaction	(118,751)	--
Net proceeds from sale of stock and exercise of stock options and warrants	--	--
Repurchases of outstanding common stock	--	(51,103)
Dividends paid	--	--
Proceeds from short-term borrowings	--	--
Net cash (used in) provided by financing activities	(118,751)	--
(Decrease) increase in cash and cash equivalents	(123,385)	(2,070,379)
Cash and cash equivalents at beginning of period	1,063,650	3,295,300
Cash and cash equivalents at end of period	$ 940,265	$ 1,224,921
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	$ --	$ --
Common stock, options and warrants issued as compensation for consulting services	$ --	$ --

See accompanying notes to condensed financial statements

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 that was founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing and removing high doses of 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 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 FDA pre-market approval for the use of its delivery system using doxorubicin, a chemotherapy agent, 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, 2003 and 2002 and cumulative from inception (August 5, 1988) to March 31, 2003.

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, 2002, which are contained in the Company's Form 10-KSB for the year ended December 31, 2002 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: RECLASSIFICATIONS

Reclassifications have been made to reflect cost and expense accounts, particularly research and development, on a functional basis for 2002 and prior, which is consistent with the Company's current presentation.

NOTE 5: DEFERRED COSTS IN CONNECTION WITH A PROPOSED FINANCING TRANSACTION

The Company has incurred costs of $357,322 as of March 31, 2003 in connection with a proposed financing transaction. If the transaction is consummated, the costs will be allocated to the financing transaction; if the transaction is not consummated, the costs will be charged to operations.

NOTE 6: 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.

The Company has adopted Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," which 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 of SFAS No. 123.

Had compensation cost for the Company's stock option grants been determined based on the fair value at the grant dates consistent with the methodology of SFAS No. 123, the Company's net loss and net loss per share for the three months ended March 31, 2003 and 2002 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended March 31,	
	2003	2002
Net loss	$(530,641)	$ (574,939)
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	(16,978)	(8,638)
Pro forma net loss	(547,619)	(583,577)
Loss per share (basic and diluted):		
As reported	$ (0.13)	$ (0.15)
Pro forma	(0.13)	(0.15)

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 any of our current or future drug-delivery systems and uncertainties regarding our ability to obtain financial and other resources for our research, development and commercialization activities. These factors, and others, are discussed from time to time in the Company's 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. A detailed description of the cash used to fund historical operations is included 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 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.

During 2001, Delcath 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 in the Phase I trial has continued into 2003.

NCI is currently preparing a clinical trial protocol for a Phase II trial of melphalan, based on the data collected in the Phase I study. Enrollment in this Phase II study is expected to begin during 2003. The Principal Investigator at the NCI has informed the Company that he plans to publish and/or present his findings in appropriate medical forums once treatment within Phase I of the trial is completed.

We also announced that the Ethics Committee of the Sydney Melanoma Unit of the University of Sydney Sydney Cancer Centre has given us approval to proceed with a Phase III study of the Delcath drug delivery system using doxorubicin for inoperable cancer in the liver. Other potential sites are not as far along as Sydney in their preparations to participate in this clinical 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 I and 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.

Liquidity and Capital Resources

We stated in our Form 10-KSB for the year ended December 31, 2002 that, without raising any additional funds, we anticipated that our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures through at least the next 12 months. That notwithstanding, the Company intends to raise additional funds in the next 12 months. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity or the hiring of additional employees during the next 12 months unless we raise additional funds. Our cash and cash equivalents balance at March 31, 2003 was $940,265.

Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, the success or failure of our 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.

Our 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 had working capital at March 31, 2003 of $707,296. 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 December 2002, we filed a registration statement with the Securities and Exchange Commission for an underwritten public offering of securities in the form of units. Each unit will consist of shares of common stock and warrants to purchase shares of common stock. 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 The National Cancer Institute using melphalan. We also anticipate using a portion of the net proceeds to hire an additional employee to serve as Director of Research and Development.

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 included in the Company's 2002 Annual Report on Form 10-KSB. The Company has not adopted any significant new accounting policies during the three months ended March 31, 2003, but has reclassified its Statements of Operations to reflect cost and expense accounts on a functional basis for 2002 and prior.

(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 within 90 days of the filing of 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 USE OF PROCEEDS.

(a) - (c) Not applicable.

(d) Use of Proceeds. The effective date of our first registration statement, filed on Form SB-2 under the Securities Act of 1933 (no. 333-39470) relating to our initial public offering of our Common Stock, was October 19, 2000. Net proceeds to Delcath were approximately $5.4 million. From the time of receipt through March 31, 2003, approximately $4,856,000 of the net proceeds were expended as shown in the table below. The remaining net proceeds are being held in temporary investments in money market accounts.

	Actual through March 31, 2003
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin ..	$2,132,000
Phase I clinical trials using the Delcath system with melphalan	$1,078,000
Product development costs	$ 9,000
Research and development stage clinical trials for other chemotherapy Agents	$ 78,000
Repayment of indebtedness	$ 270,000
Working capital, equity raising and general corporate purposes	$1,289,000
Total	$4,856,000

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits.

99.1 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.

99.2 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.

None.

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)

/s/ THOMAS S. GROGAN

Thomas S. Grogan
Chief Financial Officer (on behalf of the registrant and as the principal financial and accounting officer of the registrant)

Date: May 15, 2003

CERTIFICATION

BY CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13a-14

I, M. S. Koly, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of DELCATH SYSTEMS, INC.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for

establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were any significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ M. S. KOLY

M. S. Koly
Chief Executive Officer
(Principal executive officer)

CERTIFICATION

BY CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13a-14

I, Thomas S. Grogan, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of DELCATH SYSTEMS, INC.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

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6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were any significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ THOMAS S. GROGAN

Thomas S. Grogan
Chief Financial Officer
(Principal financial officer)

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