DELCATH SYSTEMS INC
Form 10QSB
November 15, 2002

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 September 30, 2002

[ ] 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 November 11, 2002, there were 4,146,997 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.
Balance Sheet
(Unaudited)
September 30, 2002

Assets	September 30, 2002
Current assets:	
Cash and cash equivalents	$ 1,798,717
Certificate of deposit	370,000
Interest receivable	1,792
Prepaid insurance	3,667
Total current assets	2,174,176
Furniture and fixtures, net	14,946
Deferred costs in connection with proposed financing transaction	125,659
Due from affiliate	24,000
Total assets	$ 2,338,781

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 248,974
Total current liabilities	248,974
Stockholders' equity	
Common stock	41,470
Additional paid-in capital	19,100,228
Deficit accumulated during development stage	(17,051,891)
Total stockholders' equity	2,089,807
Total liabilities and stockholders' equity	$ 2,338,781

Delcath Systems, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Costs and expenses:				
General and administrative expenses	$ 128,889	$ 192,843	$ 591,287	813,191
Research and development costs	326,626	247,509	886,802	848,945
Total costs and expenses	455,515	440,352	1,478,089	1,662,136
Operating loss	(455,515)	(440,352)	(1,478,089)	(1,662,136)
Interest income	24,260	49,449	72,956	184,319
Interest expense	-		-	(15,571)

Net loss	$ (431,254)	$ (390,903)	$(1,405,132)	$ (1,493,388)
Common share data:				
Basic and diluted loss per share	$ (0.10)	$ (0.10)	$ (0.35)	$ (0.38)
Weighted average number of shares of common stock outstanding	4,146,997	3,903,816	4,066,747	3,903,816

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,		Cumu from i (August to Septemb
	2002	2001	
Cash flows from operating activities:			
Net loss	$ (1,405,132)	$ (1,493,388)	$(15,55
Adjustments to reconcile net loss to net cash used in operating activities			
Stock option compensation expense	-	-	2,52
Stock and warrant compensation expense issued for consulting services	-	198,000	23
Depreciation expense	5,202	3,701	1

Amortization of organization costs	-	-	4
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	66,000	65,835	(
Decrease (increase) in interest receivable	51,496	(7,294)	(
Due from affiliate	-	-	(2
Increase (decrease) in accounts payable and accrued expenses	72,894	(664,960)	24
Net cash used in operating activities	(1,209,540)	(1,898,106)	(12,51
Cash flows from investing activities:			
Purchase of furniture and fixtures	(6,652)	(13,260)	(3
Purchase of short-term investments	(370,000)	-	(2,90
Proceeds from maturities of short-term investments	1,500,000	-	2,53
Organization costs	-	-	(4
Net cash provided by (used in) investing activities	1,123,348	(13,260)	(44
Cash flows from financing activities:			
Deferred costs in connection with a proposed financing transaction	(125,659)	-	(12
Net proceeds from sale of stock and exercise of stock options and warrants	267,500	-	13,68
Dividends paid	-	-	(49
Proceeds from short-term borrowings	-	(230,000)	1,70
Net cash provided by (used in) financing activities	141,841	(230,000)	14,76
Increase (decrease) in cash and cash equivalents	55,649	(2,141,366)	1,79
Cash and cash equivalents at beginning of period...	1,743,068	5,803,577	
Cash and cash equivalents at end of period	$ 1,798,717	$ 3,662,211	$ 1,79
Cash paid for interest	$ -	$ 36,141	$ 17
Supplemental disclosure of non-cash activities:			
Conversion of debt to common stock	$ -	$ -	$ 1,70
Common stock issued for preferred stock dividends	$ -	$ -	$ 99
Conversion of preferred stock to common stock ...	$ -	$ -	$ 2

Common stock issued as compensation for stock sale	$ -	$ -	$ 51
Common stock, options and warrants issued as compensation for consulting services	$ -	$ 198,000	$ 23

Delcath Systems Inc.
(A Development Stage Company)

Notes to 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-marketing 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 (including normal recurring accruals) necessary for a fair statement of the results for the interim periods ended September 30, 2002 and 2001 and cumulative from inception (August 5, 1988) to September 30, 2002.

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, 2001, which are contained in the Company's Form 10-KSB for the year ended December 31, 2001 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: Capital Stock and Warrants

On April 3, 2002, the Company received $267,500 by completing a private placement of 243,181 shares of its Common Stock and warrants to purchase up to 20,265 shares of common stock at an exercise price of $1.32 per share that expire on April 3, 2005.

Note 6: Deferred Costs in Connection With a Proposed Financing Transaction

The Company has incurred costs of $125,659 as of September 30, 2002 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.

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 ten. 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") marks an expansion in the potential labeled usage of the Delcath system beyond doxorubicin, the chemotherapy agent used in our initial clinical trials. The patent protection for the Delcath technology was also expanded in 2001, with the issuance of a U. S. patent for the use of the Delcath system for isolated kidney perfusion. Similar patent applications are pending in several foreign countries.

In efforts to find additional potential investors and raise the profile of the Company within the investment community, management has continued to speak to potential investors and investment analysts at a series of meetings in several major U. S. cities and Europe throughout 2002.

The contracted manufacture and assembly of the commercial grade Delcath system kit was completed in 2001, with the first human use kits shipped to NCI for use in the clinical trials. We 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.

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 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. In January 2002, we announced that the New York University School of Medicine plans to proceed with the FDA-approved Phase III clinical trial using doxorubicin with the Delcath system. In April 2002, we announced that the Sydney Melanoma Unit of The University of Sydney's Sydney Cancer Centre also plans to proceed with a Phase III clinical trial using doxorubicin with the Delcath System. We continue to have discussions with both institutions to agree on a budget. If these trials receive the required approvals and proceed to accrue patients, each study will involve a portion of the total of the 122 patients that are required by the FDA to participate in the Phase III trials at several institutions. We cannot estimate the starting date or duration of either trial.

Liquidity and Capital Resources

We currently anticipate 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. 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 and short term investments balance at September 30, 2002 was $2,168,717.

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 there can be no assurance of our ever achieving consistent profitability. We had working capital at September 30, 2002 of $1,925,202. We expect to require additional working capital in the future and there can be no assurance that such working capital will be available on acceptable terms, if at all. In addition, we may need additional capital in the future to fully implement our business strategy as set forth herein.

The Company is exploring a proposed financing transaction and has incurred costs through September 30, 2002 of approximately $126,000. There is no assurance under what terms such a transaction may be consummated or that the company will be able to complete such a transaction.

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 2001 Annual Report on Form 10-KSB. The Company has not adopted any significant new accounting policies during the nine months ended September 30, 2002, 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 September 30, 2002, approximately $3,510,000 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 and certificates of deposit.

	Actual thr September 30
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin	$1,905,00
Phase I clinical trials using the Delcath system with melphalan	$741,00
Product development costs	$9,00
Research and development stage clinical trials for other chemotherapy Agents	$78,00
Repayment of indebtedness	$270,00
Working capital and general corporate purposes	$507,00
Total	$3,510,00

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)

Date: November 14, 2002

/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)

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: November 14, 2002

/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

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: November 14, 2002

/s/ Thomas S. Grogan

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