DELCATH SYSTEMS INC
Form 10QSB
August 14, 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 June 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)

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 X

As of August 9, 2002, there were 4,146,997 shares of the Issuer's common stock, $.01 par value (the "Common Stock"), issued and outstanding and 1,200,000 warrants expiring October 18, 2005 each with a right entitling the holder to purchase one share of the Issuer's Common Stock for $6.60.

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

DELCATH SYSTEMS, INC.

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Delcath Systems, Inc.
Balance Sheet
(Unaudited)
June 30, 2001

Assets	June 30, 2002
Current assets:	
Cash and cash equivalents	$ 1,012,017
Certificate of deposit	1,590,261
Interest receivable	89
Prepaid insurance	25,667
Total current assets	2,628,034
Furniture and fixtures, net	16,428
Due from affiliate	24,000

Total assets	$ 2,668,462

Liabilities and Stockholders' Equity

Current liabilities:	
Accounts payable and accrued expenses	$ 147,401
Total current liabilities	147,401
Stockholders' equity	
Common stock	41,470
Additional paid-in capital	19,100,228
Deficit accumulated during development stage	(16,620,637)
Total stockholders' equity	2,521,061
Total liabilities and stockholders' equity	$ 2,668,462

Delcath Systems, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months June
	2002	2001	2002
Costs and expenses:			
Legal, consulting and accounting fees	$ 173,772	$ 271,209	$ 495,788
Compensation and related expenses ..	163,154	135,330	328,328
Other operating expenses	86,851	146,897	198,458
Total costs and expenses	423,777	553,436	1,022,574
Operating loss	(423,777)	(553,436)	(1,022,574)
Interest income	24,838	58,099	48,696
Interest expense	--	(2,939)	--
Net loss	$ (398,939)	$ (498,276)	$ (973,878)

Common share data:			
Basic and diluted loss per share	$ (0.10)	$ (0.13)	$ (0.24)
Weighted average number of shares of common stock outstanding	$ 4,146,997	$ 3,903,816	$ 4,025,407

DELCATH SYSTEMS, INC.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

	Six Months Ended 6/30/2002	6/30/2001
Cash flows from operating activities:		
Net loss	$ (973,878)	$ (1,102,485)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock option compensation expense	--	--
Stock and warrant compensation expense	--	198,000
Depreciation expense	3,468	2,388
Amortization of organization costs	--	--
Changes in assets and liabilities		
Decrease (increase) in prepaid expenses	44,000	45,835
Decrease (increase) in interest receivable	967	(10,671)
Due from affiliate	--	--
(Decrease) increase in accounts payable and accrued expenses	(28,679)	(599,490)
Net cash used in operating activities	(954,122)	(1,466,423)
Cash flows from investing activities:		
Purchase of furniture and fixtures	(6,400)	(9,952)
Purchase of short-term investments	(1,590,261)	--
Proceeds from maturities of short-term investments	--	--
Organization costs	--	--
Net cash used in investing activities	(1,596,661)	(9,952)
Cash flows from financing activities:		

Net proceeds from sale of stock and exercise of stock options and warrants	267,500	--
Dividends paid	--	--
Proceeds from short-term borrowings	--	--
Net cash provided by financing activities	267,500	--
(Decrease) increase in cash and casts	(2,283,283)	(1,476,375)
Cash and cash equivalents at beginning of period	3,295,300	5,803,577
Cash and cash equivalents at end of period	$ 1,012,017	$ 4,327,202
Cash paid for interest	$ --	$ 36,141
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	$ --	$ 198,000

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 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 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 June 30, 2002 and 2001 and cumulative from inception (August 5, 1988) to June 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 and Form 10-KSB/A for the year ended December 31, 2001 as filed with the Securities and Exchange Commission.

Note 3: Development Expenses

The Company considers that substantially all of its efforts are directed toward development of its proprietary drug delivery system and activities in support of such development. Such development expenses for the three and six months ended June 30, 2002 amounted to $257,710 and $560,176, respectively.

Note 4: 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 $1.32 per share until April 3, 2005.

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 over at least the next three years. 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 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 system for isolated kidney perfusion. Similar 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 continued to speak to potential investors and investment analysts at a series of meetings in several major U. S. cities and Europe during the first half of 2002. Management expects to continue scheduling such meetings in the second half of 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 the Delcath System. The NYU trial is pending approval by their Institutional Review Board. Both trials are pending budget approval by the respective institution. 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 June 30, 2002 was $2,602,278.

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 June 30, 2002 of $2,480,633. 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.

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

Not Applicable.

PART II
OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds.

(a) - (b) Not applicable.

(c) Recent Sales of Unregistered Securities. On April 3, 2002, we sold 243,181 shares of our Common Stock and warrants to purchase up to 20,265 shares of our Common Stock at $1.32 per share until April 3, 2005. We

received proceeds of $267,500. There were no underwriting costs associated with this transaction. An exemption from registration was claimed under Rule 506 of Regulation D.

(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 June 30, 2002, approximately $3,079,000 of the net proceeds were expended as shown in the table below. The remaining net proceeds are being held in temporary investments in short-term commercial paper.

	Actual throug June 30, 2002
Research and development:	
Phase III clinical trials using the Delcath system with doxorubicin	$1,765,000
Phase I clinical trials using the Delcath system with melphalan	$564,000
Research and development stage clinical trials for other chemotherapy agents	$78,000
Repayment of indebtedness	$270,000
Working capital and general corporate purposes	$402,000
Total	$3,079,000

Item 4. Submission of Matters to a Vote of Security Holders.

On May 23, 2002, the Company held its 2002 Annual Meeting of Stockholders. At the meeting, the stockholders voted to elect Class II directors of the Company to hold office until the Annual Meeting of Stockholders in 2005 and until their successors are elected and qualified. The stockholders voted 3,078,608 shares in favor of electing each of M. S. Koly and Samuel Herschkowitz, M.D. to serve as Class II directors and withheld the authority to vote 3,500 shares. The term of office for each of Mark Corigliano and Victor Nevins will continue until the Annual Meeting of Stockholders in 2003 and the term of office for Daniel Isdaner will continue until the Annual Meeting of Stockholders in 2004. No other matter was submitted for vote by the stockholders.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits.

Exhibit 99.1 Certification of Chief Executive 8Officer Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant To Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 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.

The Company filed a Current Report on Form 8-K, dated April 12, 2002, responding to Item 4 to announce the resignation of KPMG LLP as independent auditors for the Company and filed an

amendment to the report, dated April 12, 2002, responding to Item 4 to file the letter from KPMG LLP as required under Item 304(a)(3) of Regulation S-B.

The Company filed a Current Report on Form 8-K, dated April 26, 2002, responding to Item 4 to announce the engagement of Eisner LLP (formerly Richard A. Eisner & Company, LLP) as independent auditors for the

Company.

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: August 14, 2002

/s/ Thomas S. Grogan

Thomas S. Grogan
Chief Financial Officer (on behalf of the registrant and as the Principal Financial Officer of the registrant)