DELCATH SYSTEMS INC
Form 10QSB
November 07, 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 September 30, 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 September 30, 2003, there were 9,744,632 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.
Condensed Balance Sheet
(Unaudited)
September 30, 2003

Assets	September 30, 2003
Current assets:	
Cash and cash equivalents	$ 944,737
Certificate of deposit	2,000,000
Interest receivable	17,941
Prepaid insurance	34,540
Total current assets	2,997,218
Furniture and fixtures, net	15,035
Due from affiliate	24,000

Total assets	$ 3,036,253
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable and accrued expenses	$ 336,915
Total current liabilities	336,915
Stockholders' equity	
Common stock	97,446
Additional paid-in capital	21,777,064
Deficit accumulated during development stage	(19,175,172)
Total stockholders' equity	2,699,338
Total liabilities and stockholders' equity	$ 3,036,253

See accompanying notes to financial statements

Delcath Systems, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30, 2003	2002	Nine Months End September 30, 2003	
Costs and expenses:				
General and administrative expenses	$ 169,816	$ 128,889	$ 591,604	$
Research and development costs	508,428	326,626	1,168,434	
Total costs and expenses	678,244	455,515	1,760,038	1
Operating loss	(678,244)	(455,515)	(1,760,038)	(1

Interest income	24,133	24,260	38,671	
Interest expense	-	-	-	
Net loss	$ (654,111)	$ (431,254)	$ (1,721,367)	$ (1
Common share data:				
Basic and diluted loss per share	$ (0.07)	$ (0.10)	$ (0.26)	$
Weighted average number of shares of common stock outstanding	9,721,662	4,146,997	6,681,195	4

See accompanying notes to financial statements

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

	Nine Months Ended September 30, 2003	2002
Cash flows from operating activities:		
Net loss	$ (1,721,367)	$ (1,405,133)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock option compensation expense	-	-
Stock and warrant compensation expense	-	-
Depreciation expense	3,744	5,203
Amortization of organization costs	-	-
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses	62,043	66,000
(Increase) decrease in interest receivable	(12,535)	51,496
Due from affiliate	-	-
Increase in accounts payable and accrued expenses	161,744	172,894
Net cash used in operating activities	(1,506,371)	(1,209,540)

Cash flows from investing activities:		
Purchase of furniture and fixtures	(5,029)	(6,652)
Purchase of short-term investments	(2,000,000)	(370,000)
Proceeds from maturities of short-term investments	370,000	1,500,000
Organization costs	-	-
Net cash used in investing activities	(1,635,029)	1,123,348
Cash flows from financing activities:		
Decrease (increase) in deferred costs in connection with a proposed financing transaction	238,571	(125,659)
Net proceeds from sale of stock and exercise of stock options and warrants	2,783,916	267,500
Repurchases of outstanding common stock	-	-
Dividends paid	-	-
Proceeds from short-term borrowings	-	-
Net cash provided by financing activities	3,022,487	141,841
(Decrease) increase in cash and cash equivalents	(118,913)	55,649
Cash and cash equivalents at beginning of period	1,063,650	1,743,068
Cash and cash equivalents at end of period	$ 944,737	$ 1,798,717
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 financial statements

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 and an Investigational New Drug 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 various chemotherapy agents to treat malignant melanoma that has spread to the liver.

Note 2: Basis of Presentation

The accompanying financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended September 30, 2003 and 2002 and cumulative from inception (August 5, 1988) to September 30, 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 Annual Report on 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: 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 $2,415,064 of proceeds ($1,517,666 after underwriting fees and other expenses).

As of September 30, 2003, the Company has received $1,266,249 of net proceeds from the exercise of 2003 Warrants for which it has issued 1,730,580 shares of its common stock.

The following table sets forth changes in stockholders' equity since December 31, 2002:

	Common Stock, $.01 Par Value Outstanding		Additional
	No. of shares	Amount	Paid in Capital
Balance at December 31, 2002	4,118,897	$41,189	$19,049,406
Sale of stock May 20, 2003 including underwriter's exercise of over allot-ment option, net of related costs	3,895,155	38,952	1,478,646
Proceeds from sale of underwriters' unit option			68
Exercise of 2003 Warrants	1,730,580	17,305	1,248,944
Net loss for nine months ended September 30, 2003			
Balance at September 30, 2003	9,744,632	$97,446	$21,777,064

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.

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.

On August 25, 2003, stock options totaling 470,000 shares were granted to selected employees, nonemployees and directors. The per share weighted average fair value of the stock options for employees and directors was $.32 estimated on the date of grant using the Black-Scholes option-pricing model.

Following the methodology of SFAS No. 123 regarding compensation costs based on the fair value for all employee stock option grants, the net loss and net loss per share for the three and nine months ended September 30, 2003 and 2002 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended Sept. 30,		Nine Months Ended S	
	2003	2002	2003	
Net loss, as reported	$(654,111)	$ (431,254)	$ (1,721,367)	$
Stock-based employee compensation expense included in net loss, net of related tax effects	0	0	0	
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(18,653)	(8,638)	(50,063)	
Pro forma net loss	(672,764)	(439,892)	(1,771,430)	
Loss per share (basic and diluted):				
As reported	$ (0.07)	$ (0.10)	$ (0.26)	$
Pro forma	(0.07)	(0.11)	(0.27)	

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 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 finalized arrangements with the Sydney Melanoma Unit of the University of Sydney, Sydney Cancer Centre to proceed with recruiting patients for a Phase III study of the Delcath drug delivery system using doxorubicin for inoperable cancer in the liver.

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 will continue further through the end of 2003.

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 2004.

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.

Liquidity and Capital Resources

We stated in our Annual Report on Form 10-KSB for the year ended December 31, 2002 that, without raising any additional funds, we anticipated that our available funds would be sufficient to meet our anticipated needs for working capital and capital expenditures through at least the next 12 months. The funds we raised in our common stock offering that closed in May, discussed below, was less than we originally planned. Therefore, we intend to make efforts to raise additional funds in the next 12 months. We are not projecting any capital expenditures that will significantly affect our liquidity during the next 12 months unless we raise additional funds. Our cash and cash equivalents and certificates of deposit balance at September 30, 2003 was $2,944,737.

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 September 30, 2003 of $2,660,304. 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 the quarter ended June 30, 2003, 1,655,440 of the 2003 Warrants were exercised. During the quarter ended September 30, 2003, an additional 75,140 of the 2003 Warrants were exercised. As a result of the issuances and exercises, we received net proceeds of approximately $2.8 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.

Application of Critical Accounting Policies

Our 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 our financial statements included in our 2002 Annual Report on Form 10-KSB. We have not adopted any significant new accounting policies during the nine months ended September 30, 2003, but have reclassified our 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 5. OTHER INFORMATION

As of October 7, 2003, Paul M. Feinstein was elected as the Company's Chief Financial Officer.

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.

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)

November 6, 2003

/s/ PAUL M. FEINSTEIN

Paul M. Feinstein
Chief Financial Officer (on behalf of the registrant and as the principal financial and accounting officer of the registrant)

EXHIBIT INDEX

Exhibit No.	Description
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.