DELCATH SYSTEMS INC
Form 10QSB
November 12, 2004

UNITED STATES 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, 2004

[ ] Transition report under Section 13 or 15(d) of the Exchange Act 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 [ ]

As of October 31, 2004, there were 12,039,571 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)
September 30, 2004

Assets		September 30, 2004
Current assets:		
Cash and cash equivalents	$	920,590
Certificate of deposit		3,017,321
Interest receivable		44,795
Prepaid insurance		17,216
Total current assets		3,999,922
Furniture and fixtures, net		15,121
Due from affiliate		24,000
Total assets	$	4,039,043

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$	513,343
Total current liabilities		513,343
Stockholders' equity		
Common stock		116,859
Additional paid-in capital		25,477,468
Deficit accumulated during development stage		(22,068,627)
		(22,024,258)
Total stockholders' equity		3,525,700
Total liabilities and stockholders' equity	$	4,039,043

See accompanying notes to condensed financial statements

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

	Three Months Ended September 30, 2004	Three Months Ended September 30, 2003	Nine Months Ended September 30, 2004	Nine Months Ended September 30, 20
Costs and expenses:				
General and administrative expenses	$ 206,975	$ 169,816	$ 714,263	$ 59
Research and development costs	644,854	508,428	1,717,028	1,16
Total costs and expenses	851,829	678,244	2,431,291	1,76
Operating loss	(851,829)	(678,244)	(2,431,291)	(1,76
Other income (expense):				

Interest income	23,577	24,133	66,880	3
Interest expense	-	-	-	
Net loss	$ (828,252)	$ (654,111)	$ (2,364,411)	$ (1,72
Common share data:				
Basic and diluted loss per share	$ (0.07)	$ (0.07)	(0.22)	$ (
Weighted average number of shares of common stock outstanding	11,616,406	9,721,662	10,983,188	6,681

See accompanying notes to condensed financial statements

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

	Nine Months Ended September 30, 2004	2003	C fro (Aug to S
Cash flows from operating activities:			
Net loss	$(2,364,411)	$ (1,721,367)	$
Adjustments to reconcile net loss to net cash used in operating activities			
Stock option compensation expense	5,222	-	
Stock and warrant compensation expense issued for consulting services	-	-	
Depreciation expense	4,012	3,744	
Amortization of organization costs	-	-	
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses	30,284	62,043	
(Increase) decrease in interest receivable	(30,523)	(12,535)	
Due from affiliate	-	-	
Increase in accounts payable and accrued expenses	213,996	161,744	
Net cash used in operating activities	(2,141,420)	(1,506,371)	
Cash flows from investing activities:			

Purchase of furniture and fixtures	(5,347)	(5,029)	
Purchase of short-term investments	(2,000,000)	(2,000,000)	
Proceeds from maturities of short-term investments	1,014,575	370,000	
Organization costs	-	-	
Net cash used in investing activities	(990,772)	(1,635,029)	
Cash flows from financing activities:			
Deferred costs in connection with a proposed financing transaction	-	238,571	
Net proceeds from sale of stock and exercise of stock options and warrants	3,739,167	2,783,916	
Repurchases of outstanding common stock		-	
Dividends paid	-	-	
Proceeds from short-term borrowings	-	-	
Net cash provided by financing activities	3,739,167	3,022,487	
Increase (decrease) in cash and cash equivalents	606,975	(118,913)	
Cash and cash equivalents at beginning of period	313,615	1,063,650	
Cash and cash equivalents at end of period	$ 920,590	$ 944,737	$
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	$ -	$ -	$

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 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 premarket 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 September 30, 2004 and 2003 and cumulative from inception (August 5, 1988) to September 30, 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

During the nine months ended September 30, 2004, the Company received net proceeds of $233,291 as 266,505 of the warrants the Company issued in its public offering in 2003 were exercised as were the 20,265 warrants the Company issued in a private placement in 2002.

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 of $2,672,595 in this transaction and agreed to register the shares of common stock and the shares issuable upon exercise of the warrants under the Securites Act of 1933.

In April 2004 the Company completed an additional private placement of 290,457 shares of common stock and an aggregate of 72,614 warrants to purchase shares of its common stock, under the same terms and conditions as those sold in March 2004 for which it received net proceeds of $638,035. The Company also received during the nine months ended September 30, 2004 net proceeds of $170,673 upon the exercise of some of the Representative Unit Purchase Warrants that were issued to underwriters as part of the 2003 public offering.

The following table sets forth changes in stockholders' equity during the nine months ended September 30, 2004:

	Common Stock, $0.01 Par Value Outstanding		Additional	Deficit Accum During
	No. of shares	Amount	Paid in Capital	Development
Balance at December 31, 2003	9,744,632	$97,446	$21,777,065	$(19,704,2
Sale of common stock and warrants in March 2004, net of related costs	1,197,032	11,970	2,660,625	
Sale of common stock and warrants in April 2004, net of related costs	290,457	2,905	635,130	
Exercise of 2002 Warrants	20,265	203	26,547	
Exercise of 2003 Warrants	266,505	2,665	203,876	
Exercise of 2003 Representative's Unit Warrants	167,025	1,670	169,003	
Stock option compensation expense			5,222	
Net loss for nine months ended September 30, 2004				(2,364,
Balance at September 30, 2004	11,685,916	$116,859	$25,477,468	$(22,068,

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 and nine months ended September 30, 2004 and 2003 would have been increased to the pro forma amounts indicated as follows:

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	Three Months Ended Sept. 30, 2004	Three Months Ended Sept. 30, 2003	Nine Months 2004
Net loss, as reported	$ (828,252)	$ (654,111)	$ (2,364,411) $
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	(25,392)	(18,653)	(76,175)
Pro forma net loss	$ (853,644)	$ (672,764)	$ (2,440,586) $
Loss per share (basic and diluted):			
As reported	$ (0.07)	$ (0.07)	$ (0.22)
Pro forma	(0.07)	(0.07)	(0.22)

Note 6: Subsequent Event

On October 1, 2004, the Company issued a notice of redemption to holders of the 2003 Redeemable Common Stock Purchase Warrants. This notice, issued in accordance with the terms of the Warrants, stated that the Warrants would be redeemed as of 5:00 P.M., New York time, on November 3, 2004 (the "Redemption Date') and that any 2003 Warrant not properly exercised by the Redemption Date would thereafter represent only the right to receive the redemption price of $0.01 for each 2003 Warrant. As of October 1, 2004, there were 1,898,070 Warrants outstanding.

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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 been started. We are currently treating and recruiting patients and are in discussions with other sites worldwide.

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. The Phase I trial using melphalan has been completed.

NCI and the Company prepared clinical trial protocols for Phase II trials using melphalan, based on the data collected in the Phase I study. Enrollment and treatment of patients by the NCI in the Phase II studies began during this quarter.

Based on recommendations by a panel of leading medical oncologists and surgeons convened by the Company, the Company has drafted a Phase I protocol to treat non-operable colorectal cancer in the liver with a high-dose hepatic infusion of melphalan. This protocol is being reviewed by several major hospitals.

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 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.

Liquidity and Capital Resources

We believe that our available funds will be sufficient to meet our anticipated needs for working capital and capital expenditures at least through 2005. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. The Company has recently hired one additional employee to assist with regulatory affairs.

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.

During the nine months ended September 30, 2004, the Company had stock issuances together with exercises of previously issued warrants. Please see Note 4 to the September 30, 2004 Condensed Financial Statements included in Part I of this filing and incorporated herein by reference for a complete description of such issuances together with receipt of proceeds. 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.

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 its Annual Report on Form 10-KSB 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 nine months ended September 30, 2004.

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

Not Applicable.

(c) Off-balance Sheet Arrangements

None

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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) On August 26, 2004 and September 23, 2004, the Company sold an aggregate of 88,605 shares of its Common Stock and issued an aggregate of 88,605 Redeemable Common Stock Purchase Warrants upon the exercise of 17,721 Representative's Unit Warrants that were issued in connection with the Company's underwritten public offering in 2003. The aggregate purchase price for such shares and warrants was $90,554. The sales of these shares and warrants were made in transactions exempt from registration under Rule 506 under the Securities Act of 1933, as amended, to purchasers each of whom qualified as an "accredited investor" within the meaning of Rule 501 thereunder. No underwriting costs were associated with these transactions.

(b) Not applicable.

(c) Not applicable.

Item 6. 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.

Signatures

In accordance with the requirements of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DELCATH SYSTEMS, Inc.
(Registrant)

November 12 , 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)

EXHIBIT INDEX

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.