

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

DELCATH SYSTEMS INC  
Form 10QSB  
May 15, 2006

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-QSB

Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2006

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)

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  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of April 17, 2006, 19,541,674 shares of the Issuer's common stock, \$0.01 par value, were issued and outstanding.

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

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DELCATH SYSTEMS, INC.

Index

	Page No. -----
Part I. FINANCIAL INFORMATION	
Item 1. Condensed Financial Statements (Unaudited)	
Condensed Balance Sheet - March 31, 2006	3
Condensed Statements of Operations for the Three Months Ended March 31, 2006 and 2005 and Cumulative from Inception (August 5, 1988) to March 31, 2006	4
Condensed Statements of Cash Flows for the Three Months Ended March 31, 2006 and 2005 and Cumulative from Inception (August 5, 1988) to March 31, 2006	5
Notes to Condensed Financial Statements	6
Item 2. Management's Discussion and Analysis or Plan of Operation	9
Item 3. Controls and Procedures	11
Part II. OTHER INFORMATION	
Item 1. Legal Proceedings	11
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	11
Item 3. Defaults Upon Senior Securities	12
Item 4. Submission of Matters to a Vote of Security Holders	12
Item 5. Other Information	12
Item 6. Exhibits	12
Signatures	13

Delcath Systems, Inc.  
(A Development Stage Company)  
Balance Sheet  
(Unaudited) March 31, 2006

Assets

March 31,  
2006

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-----	
Current assets:	
Cash and cash equivalents	\$ 1,282,234
Certificates of deposit	11,850,713
Interest receivable	182,388
Prepaid insurance	43,417
-----	
Total current assets	13,358,752
Furniture and fixtures, net	6,428
-----	
Total assets	\$ 13,365,180
=====	
Liabilities and Stockholders' Equity	
Current liabilities	
Accounts payable and accrued expenses	\$ 199,093
-----	
Total current liabilities	199,093
-----	
Stockholders' equity	
Common stock, \$.01 par value, 70,000,000 shares authorized	192,907
Additional paid-in capital	39,992,485
Deficit accumulated during development stage	(27,019,305)
-----	
Total stockholders' equity	13,166,087
=====	
Total liabilities and stockholders' equity	\$ 13,365,180
=====	

See accompanying notes to condensed financial statements

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	Three Months Ended March 31,		From Inception (August 5, 1988 to March 31, 2006)
	2006	2005	
Costs and expenses:			
General and administrative expenses	\$ 561,550	\$ 415,258	\$ 9,000,750
Research and development costs	766,640	551,361	17,826,120
Total costs and expenses	1,328,190	966,619	26,826,870
Operating loss	(1,328,190)	(966,619)	(26,826,870)
Interest income	144,052	51,292	1,477,640
Interest expense	-	-	(171,470)
Net loss	\$ (1,184,138)	\$ (915,327)	\$ (25,520,700)
Common share data:			
Basic and diluted loss per share	\$ (0.06)	\$ (0.06)	
Weighted average number of shares of common stock outstanding	19,205,957	15,358,028	

See accompanying notes to condensed financial statements

4

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

	Three Months Ended March 31,		Cumulative from inception (August 5, 1988) to March 31, 2006
	2006	2005	
Cash flows from operating activities:			
Net loss	\$ (1,184,138)	\$ (915,327)	\$ (25,520,700)
Adjustments to reconcile net			

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loss to net cash used in operating activities			
Stock option compensation expense	505,282	-	3,038,94
Stock and warrant compensation expense issued for consulting services	-	-	339,71
Depreciation expense	1,126	1,515	38,87
Amortization of organization costs	-	-	42,16
Changes in assets and liabilities:			
Increase in prepaid expenses	(16,500)	(16,514)	(43,41)
Increase in interest receivable	(90,814)	(9,202)	(182,38)
(Decrease) increase in accounts payable and accrued expenses	(130,977)	57,602	199,09
	-----	-----	-----
Net cash used in operating activities	(916,021)	(881,927)	(22,087,72)
	-----	-----	-----
Cash flows from investing activities:			
Purchase of furniture and fixtures	-	-	(45,29)
Purchase of short-term investments	(1,800,000)	(1,047,077)	(23,867,49)
Proceeds from maturities of short-term investments	1,047,077	3,055,129	12,016,78
Organization costs	-	-	(42,16)
	-----	-----	-----
Net cash (used in) provided by investing activities	(752,923)	2,008,052	(11,938,17)
	-----	-----	-----
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	1,247,047	289,227	34,153,80
Repurchases of outstanding common stock	-	-	(51,10)
Dividends paid	-	-	(499,53)
Proceeds from short-term borrowings	-	-	1,704,96
	-----	-----	-----
Net cash provided by financing activities	1,247,047	289,227	35,308,13
	-----	-----	-----
(Decrease) increase in cash and cash equivalents	(421,897)	1,415,352	1,282,23
Cash and cash equivalents at beginning of period	1,704,131	202,335	
	-----	-----	-----
Cash and cash equivalents at end of period	\$ 1,282,234	\$ 1,617,687	\$ 1,282,23
	=====	=====	=====
Cash paid for interest	\$ -	\$ -	\$ 171,47
	=====	=====	=====
Supplemental disclosure of non-cash activities:			
Conversion of debt to common stock	\$ -	\$ -	\$ 1,704,96
	=====	=====	=====
Common stock issued for preferred stock dividends	\$ -	\$ -	\$ 999,07
	=====	=====	=====
Conversion of preferred stock to common stock	\$ -	\$ -	\$ 24,16
	=====	=====	=====
Common stock issued as compensation for stock sale	\$ -	\$ -	\$ 510,00
	=====	=====	=====

See accompanying notes to condensed financial statements

5

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 (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 pre-market approvals for the use of its delivery system using doxorubicin and melphalan, chemotherapeutic agents, to treat malignant melanoma that has spread to the liver.

Note 2: Basis of Presentation

The accompanying condensed 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, 2006 and 2005 and cumulative from inception (August 5, 1988) to March 31, 2006.

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, 2005, which are contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2005 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: Stockholders' Equity

During the three months ended March 31, 2006, the Company received net proceeds

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of \$1,247,047 as 91,440 of the March 2004 Warrants were exercised and 349,573 of the November 2004 Warrants were exercised for which it has issued shares of its common stock.

6

The following table sets forth changes in stockholders' equity during the three months ended March 31, 2006:

	Common Stock, \$0.01 Par Value Issued and Outstanding		Additional	Deficit
	No. of shares	Amount	Paid in Capital	Development
	-----	-----	-----	-----
Balance at December 31, 2005	18,849,653	\$188,497	\$38,244,566	\$ (25,000)
Issuance of common stock in connection with the exercise of 2004 Warrants	441,013	4,410	1,242,637	
Vesting of stock options	-	-	505,282	
Net loss for three months ended March 31, 2006				(1,000)
Balance at March 31, 2006	19,290,666	\$192,907	\$39,992,485	\$ (26,000)
	=====	=====	=====	=====

Note 5: Stock Option Plan

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R). This Statement is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), and its related implementation guidance. SFAS 123R establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant). Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB 25, as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant. The Company also followed the disclosure requirements of SFAS 123 as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". Effective January 1, 2006, the Company adopted the modified prospective approach and accordingly, prior period amounts have not been restated. Under this approach, the Company is required to record compensation cost for all share-based payments granted after the date of adoption based on the grant date fair value, estimated in accordance with the provisions of SFAS 123R, and for the unvested portion of all share-based payments previously

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granted that remain outstanding based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123. The Company will expense its share-based compensation for share based payments granted after January 1, 2006 under the ratable method, which treats each vesting tranche as if it were an individual grant. Adoption of this standard had no significant impact on the Company's financial condition or results of operations.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of our common stock at the date of the grant. The Company estimates the fair value of stock options using a Black-Scholes valuation model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of our stock over the option's expected term, the risk-free interest rate over the option's expected term, and our expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards. There have been no share-based payments granted in 2006.

The required adoption of SFAS No. 123R as of January 1, 2006 is expected to significantly increase compensation expense for future grants. The actual impact on future years will be dependent on a number of

7.

factors, including our stock price and the level of future grants and awards. In addition, costs related to accounting and valuation services of stock options currently outstanding in accordance with SFAS No. 123R would have been cost prohibitive to the Company if the Company had not adopted certain measures. Based on these considerations and after discussion of applicable accounting literature, the Compensation Committee of the Board of Directors approved accelerating the vesting of all unvested stock options effective January 1, 2006. Unvested options having exercise prices of \$2.78 and \$3.59 per share, representing the right to purchase a total of approximately 1 million shares, became exercisable as a result of the vesting acceleration. All other terms and conditions in the original grants remain unchanged. The acceleration of vesting resulted in the recognition of non cash compensation expense of \$505,282 on January 1, 2006 which is included in general and administrative expenses and research and development costs in the statements of operations.

Prior to January 1, 2006, the Company accounted for stock-based compensation plans in accordance with the provisions of APB 25, as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant. There were no share-based grants during the three-month period ended March 31, 2005. 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 months ended March 31, 2005 would have been increased to the pro forma amounts indicated as follows:

Net loss, as reported	\$ (915,327)
Stock-based employee compensation expense included in net loss, net of related	



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tax effects	0
Stock-based employee compensation determined under the fair value based method, net of related tax effects	(17,618)
	-----
Pro forma net loss	(932,945)
	=====
Loss per share (basic and diluted):	
As reported	\$ (0.06)
Pro forma	(0.06)

The Company established an Incentive Stock Option Plan, a Non-Incentive Stock Option Plan, the 2000 Stock Option Plan, the 2001 Stock Option Plan and the 2004 Stock Incentive Plan (collectively, the "Plans") under which stock options, stock appreciation rights, restricted stock, and stock grants may be awarded. A stock option grant allows the holder of the option to purchase a share of the Company's Common Stock in the future at a stated price. The Plans are administered by the Compensation Committee of the Board of Directors which determines the individuals to whom the options shall be granted as well as the terms and conditions of each option grant, the option price and the duration of each option.

The Company's Incentive and Non-Incentive Stock Option Plans were approved and became effective on November 1, 1992. During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and the

8.

2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. All outstanding options are fully vested. Stock option activity for the three-month period ended March 31, 2006 is as follows:

	The Plans		
	Stock Options	Exercise Price Per Share	Weighted Average Exercise Price
	-----	-----	-----
Outstanding at December 31, 2005	1,385,800	\$0.71 - \$3.59	\$2.51
Granted	0		
Expired	0		
Exercised	0		
	-----		
Outstanding at March 31, 2006	1,385,800	\$.71 - \$3.59	\$2.51

=====

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 and the clinical trials of our product, and the pursuit of patents worldwide. We expect to continue to incur significant losses from costs 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 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 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 chemotherapeutic agent, melphalan. The Phase I trial at the National Cancer Institute marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapeutic agent used in our initial clinical trials.

9.

Enrollment of new patients in the Phase I trial was completed in 2003 and following the 2004 presentation and adoption of a Phase II clinical trial protocol, patients are being enrolled and treated.

During 2004, we commenced a Phase III clinical trial study of the Delcath drug delivery system for inoperable cancer in the liver using doxorubicin. We are

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currently recruiting additional sites worldwide.

In 2005, we started enrolling and treating patients in a Phase III protocol for the study of the Delcath drug delivery system for inoperable cancer in the liver using melphalan.

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 melphalan and doxorubicin with the Delcath system and Phase 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. 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 expect our available funds to be sufficient for our anticipated needs for working capital and capital expenditures through 2007 provided no studies using new agents or treating new organs are initiated. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. The Company is projecting the hiring of one additional employee.

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. The Company has operated at a loss for its entire history and there can be no assurance of its ever achieving consistent profitability. The Company believes its capital resources are adequate to fund operations for at least the next twelve months but anticipates that it will require additional working capital after 2007 or earlier if new studies or trials are initiated. There can be no assurance that such working capital will be available on acceptable terms, if at all.

During the three months ended March 31, 2006, the Company had exercised of previously issued warrants. Please see Note 4 to the March 31, 2006 Condensed Financial Statements included in Part I of this filing and incorporated herein by reference for a complete description of share 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 III clinical trial at National Cancer Institute using melphalan.

10.

Application of Critical Accounting Policies

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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 the Company's Annual Report on Form 10-KSB for the year ended December 31, 2005 as filed with the Securities and Exchange Commission. The Company has not adopted any significant new accounting policies or modified the application of existing policies during the three months ended March 31, 2006.

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

Not Applicable.

- (c) Off-balance sheet arrangements

The Company does not have any off-balance sheet arrangements.

### 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 1. Legal Proceedings

None

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On January 9, 2006, the Company sold an aggregate of 319,570 shares of its Common Stock upon exercise of 41,494 of then outstanding Warrants to Purchase Shares of Common Stock dated March 19, 2004 and 278,076

11.

of then outstanding Warrants to Purchase Shares of Common Stock dated November 24, 2004. The Company received an aggregate of \$897,948 upon such exercises. On February 1, 2006, the Company sold an aggregate of 65,674 shares of its Common Stock upon exercise of 29,926 of then outstanding Warrants to Purchase Shares of Common Stock dated March 19, 2004 and 35,748 of then outstanding Warrants to Purchase Shares of Common Stock dated November 24, 2004. The Company received an aggregate of \$189,457 upon such exercises. On February 21, 2006, the Company sold an aggregate of 55,769 shares of its Common Stock upon exercise of 20,020 of then outstanding Warrants to Purchase Shares of Common Stock dated March 19, 2004 and 35,749 of then outstanding Warrants to Purchase Shares of Common Stock dated November 24, 2004. The Company received an aggregate of \$159,642 upon such exercises. The Company claims an exemption from registration of the offer and sale of the shares of Common Stock issued upon exercise of these Warrants under Rule 506 under the Securities Act of 1933 on the basis that each of the purchasers is an accredited investor.

No underwriter was involved in the exercise of these Warrants, and the Company paid no underwriting discount or commission in connection therewith. Proceeds from the sale of securities will be used to fund current and future operations.

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

The information included in Item 2 of this report is incorporated by reference into this Item 5.

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.

12.

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## 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)

May 15, 2006

/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)

13.

## EXHIBIT INDEX

- 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.