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DELCATH SYSTEMS INC  
Form 10-Q  
May 10, 2007

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2007

TRANSITION REPORT PURSUANT TO 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 registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

06-1245881  
(I.R.S. Employer  
Identification No.)

1100 Summer Street, 3rd Floor, Stamford, CT 06905  
(Address of principal executive offices)

(203) 323-8668  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 19, 2007, 21,358,007 shares of the Company's common stock, \$0.01 par value, were issued and outstanding.

DELCATH SYSTEMS, INC.

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PART I:  
FINANCIAL INFORMATION

ITEM 1: CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

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DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED BALANCE SHEETS

|   | MARCH 31,<br>2007<br>(UNAUDITED)<br>----- | DECEMBER 31,<br>2006<br>(AUDITED)<br>----- |
|---|---|--|
| ASSETS  |   |  |
| Current assets  |   |  |
| Cash and cash equivalents                                   | \$ 7,574,247                              | \$ 6,242,117                               |
| Certificates of deposit                                     | 540,972                                   | 2,111,111                                  |
| Prepaid expenses  | 311,417                                   | 1,111,111                                  |
| Total current assets  | \$ 8,426,636                              | \$ 9,464,339                               |
| Property and equipment, net                                 | 11,490                                    | 11,490                                     |
| Total assets  | \$ 8,438,126                              | \$ 9,475,829                               |
| LIABILITIES AND STOCKHOLDERS' EQUITY                        |   |  |
| Current liabilities   |   |  |
| Accounts payable and accrued expenses                       | 275,942                                   | 275,942                                    |
| Total current liabilities                                   | \$ 275,942                                | \$ 275,942                                 |
| Commitments and contingencies                               | -   | -  |
| Stockholders' equity  |   |  |
| Common stock, \$.01 par value; 70,000,000 shares authorized | \$ 212,727                                | \$ 212,727                                 |
| Additional paid-in capital                                  | 46,010,343                                | 44,010,343                                 |
| Deficit accumulated during development stage                | (38,060,886)                              | (36,010,343)                               |
| Total stockholders' equity                                  | \$ 8,162,184                              | \$ 8,212,727                               |
| Total liabilities and stockholders' equity                  | \$ 8,438,126                              | \$ 9,475,829                               |

SEE ACCOMPANYING NOTES TO CONDENSED FINANCIAL STATEMENTS.

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DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENTS OF OPERATIONS

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(UNAUDITED)

|  | THREE MONTHS ENDED<br>MARCH 31, |                | CUMULATIVE FROM<br>INCEPTION<br>(AUGUST 5, 1988)<br>TO<br>MARCH 31, |
|--|---------------------------------|----------------|---|
|  | 2007                            | 2006           | 2007  |
| <b>COSTS AND EXPENSES:</b>                                       |                                 |                |   |
| General and administrative expenses                              | \$ 500,819                      | \$ 561,550     | \$ 17,920,448   |
| Research and development costs                                   | 888,951                         | 766,640        | 20,666,515  |
|  | -----                           | -----          | -----   |
| Total costs and expenses   | \$ 1,389,770                    | \$ 1,328,190   | \$ 38,586,963   |
|  | -----                           | -----          | -----   |
| Operating loss   | \$ (1,389,770)                  | \$ (1,328,190) | \$ (38,586,963)   |
| Interest income  | 115,656                         | 144,052        | 2,069,655   |
| Other income   | -                               | -              | 126,500   |
| Interest expense   | -                               | -              | (171,473)   |
|  | -----                           | -----          | -----   |
| Net loss   | \$ (1,274,114)                  | \$ (1,184,138) | \$ (36,562,281)   |
|  | =====                           | =====          | =====   |
| <b>COMMON SHARE DATA:</b>  |                                 |                |   |
| Basic and diluted loss per share                                 | \$ (0.06)                       | \$ (0.06)      |   |
|  | =====                           | =====          |   |
| Weighted average number of shares<br>of common stock outstanding | \$ 21,004,943                   | \$ 19,205,957  |   |
|  | =====                           | =====          |   |

SEE ACCOMPANYING NOTES TO CONDENSED FINANCIAL STATEMENTS.

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DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

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### CASH FLOWS FROM OPERATING ACTIVITIES:

|   |                |
|---|----------------|
| Net loss  | \$ (1,274,114) |
| Adjustments to reconcile net loss to net cash used in operating activities:             |                |
| Stock option compensation expense   | -              |
| Stock and warrant compensation expense issued for legal settlement, consulting services | -              |
| Depreciation expense  | 969            |
| Amortization of organization costs  | -              |
| Changes in assets and liabilities:  |                |
| Increase in prepaid expenses  | (249,500)      |
| Increase in interest receivable   | -              |
| (Decrease) increase in accounts payable and accrued expenses                            | (394,425)      |
|   | -----          |
| Net cash used in operating activities   | \$ (1,917,070) |
|   | -----          |

### CASH FLOWS FROM INVESTING ACTIVITIES:

|   |              |
|---|--------------|
| Purchase of property and equipment                  | \$ (8,740)   |
| Purchase of short-term investments                  | -            |
| Proceeds from maturities of short-term investments  | 1,867,330    |
| Organization costs                                  | -            |
|   | -----        |
| Net cash provided by (used in) investing activities | \$ 1,858,590 |
|   | -----        |

### CASH FLOWS FROM FINANCING ACTIVITIES:

|  |              |
|--|--------------|
| Net proceeds from sale of stock and exercise of stock options and warrants | \$ 1,343,004 |
| Repurchases of common stock  | -            |
| Dividends paid   | -            |
| Proceeds from short-term borrowings  | -            |
|  | -----        |
| Net cash provided by financing activities                                  | \$ 1,343,004 |
|  | -----        |

|  |           |
|--|-----------|
| Increase (decrease) in cash and cash equivalents | 1,284,524 |
| Cash and cash equivalents at beginning of period | 6,289,723 |
|  | -----     |

|  |              |
|--|--------------|
| Cash and cash equivalents at end of period | \$ 7,574,247 |
|  | =====        |

### SUPPLEMENTAL CASH FLOW INFORMATION:

|                        |       |
|------------------------|-------|
| Cash paid for interest | -     |
|                        | ===== |

### SUPPLEMENTAL NON-CASH ACTIVITIES:

|  |       |
|--|-------|
| Cashless exercise of stock options                 | -     |
| 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.

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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 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 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 separate FDA pre-market approvals for the use of its delivery system using Melphalan, a chemotherapeutic agent, to treat malignant melanoma that has spread to the liver.

### NOTE 2: BASIS OF FINANCIAL STATEMENT PRESENTATION

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP"). 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, 2007 and 2006, and cumulative from inception (August 5, 1988) to March 31, 2007.

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, 2006, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission (the "SEC") on March 16, 2007.

### NOTE 3: COSTS AND EXPENSES

#### 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.

#### GENERAL AND ADMINISTRATIVE COSTS

General and administrative costs include the Company's general and administrative operating expenses.

### NOTE 4: STOCKHOLDERS' EQUITY

The Company received a net amount of \$1,343,004 upon the exercise of stock options for 611,850 shares during the three months ended March 31, 2007. Of those options: (i) 100,000 were exercised at a price of \$0.71 per share, (ii) 120,000 were exercised at a price of \$1.03 per share, (iii) 20,000 were

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exercised at a

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DELCATH SYSTEMS, INC.  
 (A DEVELOPMENT STAGE COMPANY)  
 NOTES TO CONDENSED FINANCIAL STATEMENTS

price of \$1.32 per share, (iv) 200,000 were exercised at a price of \$2.78 per share, (v) 100,000 were exercised at a price of \$3.28 per share, and (vi) 71,850 were exercised at a price of \$3.31 per share.

The following table sets forth changes in stockholders' equity during the three months ended March 31, 2007:

|   | COMMON STOCK,<br>\$0.01 PAR VALUE<br>ISSUED AND OUTSTANDING |            | ADDITIONAL PAID<br>IN CAPITAL | DEFICIT<br>DURING |
|---|---|------------|-------------------------------|-------------------|
|   | NO. OF SHARES   | AMOUNT     |                               |                   |
| Balance at December 31, 2006                      | 20,660,763  | \$ 206,608 | \$ 44,673,458                 | \$                |
| Exercise of stock options                         | 611,850   | 6,119      | 1,336,885                     |                   |
| Net loss for three months ended<br>March 31, 2007 |   |            |                               |                   |
| Balance at March 31, 2007                         | 21,272,613  | \$ 212,727 | \$ 46,010,343                 | \$                |

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 option holders' 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 upon

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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 granted that remain outstanding based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123. The Company has expensed 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.

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

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DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONDENSED FINANCIAL STATEMENTS

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 were no share-based grants in 2007.

The required adoption of SFAS No. 123R as of January 1, 2006 has significantly increased compensation expense for future grants. The actual impact on future years will be dependent on a number of 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. The acceleration of vesting resulted in the recognition of a non-cash compensation expense of \$505,282 on January 1, 2006 which is included in costs and expenses in the statements of operations for 2006.

The Company established its Incentive Stock Option Plan, Non-Incentive Stock Option Plan, 2000 Stock Option Plan, 2001 Stock Option Plan and 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 and Stock Option 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.

During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and 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 currently outstanding options are fully vested. Stock option activity for the three-month period ended March 31, 2007 is as follows:



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| THE PLANS                        |               |                             |                                       |
|----------------------------------|---------------|-----------------------------|---------------------------------------|
|                                  | STOCK OPTIONS | EXERCISE PRICE<br>PER SHARE | WEIGHTED<br>AVERAGE<br>EXERCISE PRICE |
| Outstanding at December 31, 2006 | 1,465,650     | \$0.71 - \$3.59             | \$2.87                                |
| Granted                          | -             | -                           | -                                     |
| Expired                          | 202,500       | \$3.59                      | \$3.59                                |
| Exercised                        | 611,850       | \$0.71 - \$3.31             | \$2.19                                |
| Outstanding at March 31, 2007    | 651,300       | \$1.03 - \$3.59             | \$3.28                                |

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DELCATH SYSTEMS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONDENSED FINANCIAL STATEMENTS

NOTE 6: INCOME TAXES

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 9" ("FIN No. 48"), on January 1, 2007. FIN No. 48 requires that the impact of tax positions be recognized in the financial statements if they are more likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the consolidated financial statements in the 2006 Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion, or all of its deferred tax assets, will not be realized. The Company has not recognized any unrecognized tax benefits in their balance sheet under the provisions of FIN No. 48. In addition, there is no impact to accumulated deficit at the date of adoption as a result of the implementation of FIN No. 48.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the I.R.S. or any states in connection with income taxes. The periods from 2004 - 2006 remain open to examination by the I.R.S. and state authorities.

We recognize interest accrued related to unrecognized tax benefits in interest expense. Penalties, if incurred, are recognized as a component of income tax expense.

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### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### FORWARD LOOKING STATEMENTS

Certain statements in this Form 10-Q, including statements of our and management's expectations, intentions, plans, objectives and beliefs, including those contained in or implied by "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that is subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expansion and possible results from expansion, our expected growth, our capital budget and future capital requirements, the availability of funds and our ability to meet future capital needs, the realization of our deferred tax assets, and the assumptions described in this report underlying such forward-looking statements. Actual results and developments could differ materially from those expressed in or implied by such statements due to a number of factors, including without limitation, those described in the context of such forward-looking statements, our expansion strategy, our ability to achieve operating efficiencies, industry pricing and technology trends, evolving industry standards, domestic and international regulatory matters, general economic and business conditions, the strength and financial resources of our competitors, our ability to find and retain skilled personnel, the political and economic climate in which we conduct operations, the risks discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, filed with the SEC on March 16, 2007 (the "2006 Form 10-K"), under Item 1, "Description of Business," and other risk factors described from time to time in our other documents and reports filed with the Securities and Exchange Commission (the "SEC"). We do not assume any responsibility to publicly update any of our forward-looking statements regardless of whether factors change as a result of new information, future events or for any other reason. We advise you to review any additional disclosures we make in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Reports on Form 10-K filed with the SEC.

#### 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, as described in our 2006 Form 10-K under Item 1, "Patents, Trade Secrets and Proprietary Rights." 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. Enrollment of new patients in the Phase I trial was completed in 2003.

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In 2004, we commenced a Phase II clinical trial protocol for the study of the Delcath drug delivery system for inoperable primary liver cancer and adenocarcinomas and neuroendocrine cancers that have metastasized to the liver using Melphalan.

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In 2006, we started enrolling and treating patients in a Phase III protocol for the study of the Delcath drug delivery system for inoperable melanoma in the liver using Melphalan under the Fast Track and SPA approved protocol.

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 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 other cancers, 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.

### RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2007

The Company has operated at a loss for its entire history. We had a net loss for the three months ended March 31, 2007, of \$1,274,114, which is \$89,976 more than the net loss from continuing operations for the same period in 2006. This increased loss was primarily due to additional expenses relating to a Settlement Agreement in connection with the lawsuit brought by the Company against Jonathan Foltz, which was previously disclosed in our 2006 Form 10-K.

General and administrative expenses decreased from \$561,550 during the three months ended March 31, 2006, to \$500,819 for the three months ended March 31, 2007, or 10.8%. This decrease is primarily attributed to the charge to operations of share-based compensation for options granted in November 2006, which occurred during the three months ended March 31, 2006 as part of the adoption of SFAS 123R as explained in "Note 5: Stock Option Plan" of the Notes to Condensed Financial Statements filed with this Report. There was no similar charge during the three months ended March 31, 2007.

During the first quarter of 2007, we incurred \$888,951 in research and development costs, as compared to \$766,640 during the first quarter of 2006. This increase is primarily due to expenses relating to a five year extension to the Company's Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") that expired in December 2006. This extension was quite important in continuing and expanding the collaboration between the Company and the NCI, but will result in greater costs to the Company.

Interest income shown is from our money market and CD investments. During the three months ended March 31, 2007, the Company had interest income of \$115,656, as compared to interest income of \$144,052, or a 19.7% change, for the same period in 2006. This decrease is primarily due to a reduced cash position in 2007 from that in 2006. There was no other income during the three months ended March 31, 2007 or the comparable period in 2006.

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### LIQUIDITY AND CAPITAL RESOURCES

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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 is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. However, 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. In addition, the Company intends to hire one additional employee.

At March 31, 2007, we had cash and cash equivalents of \$7,574,247, as compared to \$6,289,723 at December 31, 2006 and \$1,282,234 at March 31, 2006. Because money market rates have been equal to or greater than what the Company could receive in CD investments, nearly all of our funds are currently invested in money market accounts which are shown in our financial statements as part of "Cash and Cash Equivalents." In the quarter ended March 31, 2006, the majority of our funds had been invested in CDs that became due during 2006.

During the three months ended March 31, 2007, we used \$1,917,070 of cash in our operating activities. This amount compares to \$916,021 used in our operating activities during the comparable three-month period in 2006. The increase of \$1,001,047 was primarily due to payments to NCI as part of our newly extended CRADA agreement, and final payments to various parties as part of the settlements of the lawsuits that had commenced in 2006.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003. Please see the detailed discussion of our various sales of securities described in Note 2 to our 2006 financial statements in our 2006 Form 10-K. In addition, we received proceeds of approximately \$5.6 million from private placements we completed in 2004, approximately \$2.2 on exercise of warrants and options in 2004, approximately \$2.5 million from a private placement we completed in 2005, approximately \$5.5 million on exercise of warrants and options in 2005; and approximately \$5.1 million on exercise of warrants and options in 2006. In the quarter ended March 31, 2007, we received approximately \$1.3 million on exercise of warrants and options.

While the Company has sufficient capital to conduct its operations through the end of 2007, it requires additional capital for research and development and for additional clinical trials. Accordingly, simultaneously with the filing of this Report, the Company is filing a Registration Statement on Form S-3 (the "Registration Statement") to register an offering of common stock, preferred stock, debt securities, warrants, stock purchase contracts and stock purchase units, as may from time to time be issued, with a maximum offering price of \$17,200,000, in order to raise additional funds. However, there are no assurances that the Registration Statement will become effective or that the Company will successfully consummate any transactions under the offerings, nor can the Company estimate when, if such offerings are successful, these offerings may close and capital will become available to the Company. If the offerings are successful, the Company intends to use the funds raised for research and development, furthering our clinical trials, FDA compliance, and general corporate purposes, including working capital.

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### 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 ("GAAP"). 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 2006 Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP. The Company has not adopted any significant new accounting policies or modified the application of existing policies during the three months ended March 31, 2007.

Additionally, the Company devotes substantial resources to clinical trials and other research and development activities relating to obtaining FDA and other approvals for the Delcath system, the cost of which is required to be charged to expense as incurred. This further limits the Company's choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying SFAS No. 109, "Accounting for Income Taxes," management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets.

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123R supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123. However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The Company adopted SFAS 123R in 2006.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company does not use derivative financial instruments. The Company's marketable securities consist of short-term and/or variable rate instruments and, therefore, a change in interest rates would not have a material impact on the value of these securities.

### ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of the Company's disclosure controls and procedures performed by the Company's Chief Executive Officer and Chief Financial Officer as of the end of the period covered by this report, the Company's Chief Executive Officer and 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 of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and

forms issued by the SEC. 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 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.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation described above that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II:  
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We have been involved in a legal proceeding that was originally filed on August 12, 2005 in the United States District Court, District of Connecticut against Elizabeth L. Enney. The named plaintiffs are Delcath Systems, Inc. and M.S. Koly (former CEO, President, Treasurer and Director of Delcath), individually and as a Director of Delcath Systems, Inc. The operative complaint seeks damages for libel. In May 2006, the libel claims were dismissed for lack of personal jurisdiction, and in July 2006, Plaintiffs filed a new libel claim in the United States District Court for the Northern District of Georgia. On November 1, 2006, Defendant filed a Motion for Judgment claiming that Plaintiffs' complaint and the attachments thereto, on their face, were insufficient to support Plaintiffs' libel claim as a matter of law. On December 22, 2006, Defendant filed a motion under Rule 11 of the Federal Rules of Civil Procedure seeking an order directing payment to the Defendant of reasonable attorneys' fees and expenses by Plaintiff. On April 19, 2007, the entire action was ordered and adjudged to be dismissed, and the Defendant was granted recovery of its costs.

ITEM 1A. RISK FACTORS

Our 2006 Form 10-K contains a detailed discussion of certain risk factors that could materially adversely affect our business, operating results or financial condition. The following risk factor has been amended and updated to reflect recent events, and should be read in conjunction with the risk factors and information disclosed in the 2006 Form 10-K.

OUR COMMON STOCK IS LISTED ON THE NASDAQ CAPITAL MARKET. IF WE FAIL TO MEET THE REQUIREMENTS OF THE NASDAQ CAPITAL MARKET FOR CONTINUED LISTING, OUR COMMON STOCK COULD BE DELISTED.

Our common stock is currently listed on the NASDAQ Capital Market. To keep such listing, we are required to maintain: (i) a minimum bid price of \$1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least \$500,000, a market value of listed securities of at least \$35 million or a stockholders' equity of at least \$2.5 million. We were notified by the NASDAQ Capital Market on one occasion that we failed to meet the minimum bid price requirement and on two occasions that we did not meet the requirement that

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we meet one of the following conditions: that the market value of our common stock be at least \$35 million; that we have stockholders' equity of not less than \$2.5 million; or that we meet certain income tests. We have since complied with these requirements.

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We are also required to maintain certain corporate governance requirements. On April 30, 2007, we were notified by NASDAQ that due to the resignations of two of our independent directors on April 16, 2007, we no longer comply with NASDAQ's requirements to have a majority of independent directors on our Board of Directors, and for our Audit Committee to have three members. The Company fully intends to regain compliance with both of these requirements within the cure period allowed by NASDAQ (i.e., by October 13, 2007). If we do not regain compliance by then, our common stock could be delisted from the NASDAQ Capital Market. In addition, if we fail to meet any of the other applicable criteria, our common stock could be delisted from the NASDAQ Capital Market.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

### ITEM 5. OTHER INFORMATION

There were no matters required to be disclosed in a Current Report on Form 8-K during the fiscal quarter covered by this report that were not so disclosed.

There were no changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors since the Company last disclosed such procedures in our proxy statement filed in connection with our annual meeting of stockholders to be held on June 5, 2007.

### ITEM 6. EXHIBITS

31.1 Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

31.2 Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

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.

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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.

May 10, 2007

DELCATH SYSTEMS, INC.  
(Registrant)

/S/ PAUL M. FEINSTEIN

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

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