

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

DELCATH SYSTEMS INC
Form 10QSB
November 14, 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 September 30, 2006

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)

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 November 6, 2006, 20,660,763 shares of the Issuer's common stock, \$0.01 par value, were issued and outstanding.

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

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

DELCATH SYSTEMS, INC.

Index

| | Page No. ----- |
|---|-------------------|
| Part I. FINANCIAL INFORMATION | |
| Item 1. Condensed Financial Statements (Unaudited) | |
| Condensed Balance Sheet - September 30, 2006 | 3 |
| Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2006 and 2005 and Cumulative from Inception (August 5, 1988) to September 30, 2006 | 4 |
| Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2006 and 2005 and Cumulative from Inception (August 5, 1988) to September 30, 2006 | 5 |
| Notes to Condensed Financial Statements | 6 |
| Item 2. Management's Discussion and Analysis or Plan of Operation | 10 |
| Item 3. Controls and Procedures | 11 |
| Part II. OTHER INFORMATION | |
| Item 1. Legal Proceedings | 12 |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds | 13 |
| Item 3. Defaults Upon Senior Securities | 13 |
| Item 4. Submission of Matters to a Vote of Security Holders | 13 |
| Item 5. Other Information | 13 |
| Item 6. Exhibits | 13 |
| Signatures | 14 |

Delcath Systems, Inc.
(A Development Stage Company)
Condensed Balance Sheet

(Unaudited)
September 30, 2006

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

| Assets | September 30, 2006 |
|---|-----------------------|
| | ----- |
| Current assets: | |
| Cash and cash equivalents | \$ 7,113,000 |
| Cash held in trust | 3,016,247 |
| Certificates of deposit | 2,378,454 |
| Prepaid insurance | 26,417 |
| | ----- |
| Total current assets | 12,534,118 |
| Furniture and fixtures, net | 4,551 |
| | ----- |
| Total assets | \$ 12,538,669 |
| | ===== |
| Liabilities and Stockholders' Equity | |
| Current liabilities: | |
| Accounts payable and accrued expenses | \$ 1,775,310 |
| | ----- |
| Total current liabilities | 1,775,310 |
| | ----- |
| Contingencies (Note 6) | - |
| Stockholders' equity | |
| Common stock, \$0.01 par value, 70,000,000 shares authorized | 205,367 |
| Additional paid-in capital | 43,831,534 |
| Deficit accumulated during development stage | (33,273,542) |
| | ----- |
| Total stockholders' equity | 10,763,359 |
| | ----- |
| Total liabilities and stockholders' equity | \$ 12,538,669 |
| | ===== |

See accompanying notes to condensed financial statements

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

| | Three Months Ended September 30, 2006 | | September 30, 2005 | | Nine Months Ended September 30, 2006 | | September 30, 2005 | |
|---|---|-------------|-----------------------|------------|--|-------------|-----------------------|-------------|
| | ----- | | ----- | | ----- | | ----- | |
| Costs and expenses: | | | | | | | | |
| General and administrative expenses | \$ | 4,400,910 | \$ | 309,820 | \$ | 6,053,427 | \$ | 1,010,000 |
| Research and development costs | | 466,207 | | 395,332 | | 1,868,064 | | 1,320,000 |
| | | ----- | | ----- | | ----- | | ----- |
| Total costs and expenses | | 4,867,117 | | 705,152 | | 7,921,491 | | 2,330,000 |
| | | ----- | | ----- | | ----- | | ----- |
| Operating loss | | (4,867,117) | | (705,152) | | (7,921,491) | | (2,330,000) |
| Other income (expense): | | | | | | | | |
| Interest income | | 178,599 | | 61,399 | | 483,116 | | 160,000 |
| Interest expense | | - | | - | | - | | - |
| | | ----- | | ----- | | ----- | | ----- |
| Net loss | \$ | (4,688,518) | \$ | (643,753) | \$ | (7,438,375) | \$ | (2,170,000) |
| | | ===== | | ===== | | ===== | | ===== |
| Common share data: | | | | | | | | |
| Basic and diluted loss per share | \$ | (0.23) | \$ | (0.04) | \$ | (0.38) | \$ | (0.10) |
| | | ===== | | ===== | | ===== | | ===== |
| Weighted average number of shares of common stock outstanding | | 20,131,471 | | 16,143,367 | | 19,658,719 | | 15,667,000 |
| | | ===== | | ===== | | ===== | | ===== |

See accompanying notes to condensed financial statements

4

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

| | Nine Months Ended September 30, 2006 | | September 30, 2005 | | Cumulative from inception (August 5, 1988) to September 30, 2006 | |
|---------------------------------------|--|--|-----------------------|--|---|--|
| | ----- | | ----- | | ----- | |
| Cash flows from operating activities: | | | | | | |

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

| | | | |
|--|----------------|----------------|---------------|
| Net loss | \$ (7,438,375) | \$ (2,184,164) | \$ (31,774,93 |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Stock option compensation expense | 505,282 | 8,270 | 3,038,94 |
| Stock and warrant compensation expense issued for consulting services | - | 103,425 | 339,71 |
| Depreciation expense | 3,003 | 4,544 | 40,74 |
| Amortization of organization costs | - | - | 42,16 |
| Changes in assets and liabilities: | | | |
| Decrease (increase) in prepaid expenses | 500 | 45,646 | (26,41 |
| Decrease (increase) in interest receivable | 91,574 | (102,918) | |
| Increase (decrease) in accounts payable and accrued expenses | 1,445,240 | (342,407) | 1,775,31 |
| Net cash used in operating activities | (5,392,776) | (2,467,604) | (26,564,47 |
| Cash flows from investing activities: | | | |
| Purchase of furniture and fixtures | - | - | (45,29 |
| Purchase of short-term investments | (5,394,701) | (3,047,077) | (27,462,19 |
| Proceeds from maturities of short-term investments | 11,097,790 | 3,055,129 | 22,067,49 |
| Organization costs | - | - | (42,16 |
| Net cash provided by (used in) investing activities | 5,703,089 | 8,052 | (5,482,16 |
| Cash flows from financing activities: | | | |
| Net proceeds from sale of stock and exercise of stock options and warrants | 5,098,556 | 3,119,651 | 38,005,31 |
| 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 | 5,098,556 | 3,119,651 | 39,159,64 |
| Increase in cash and cash equivalents | 5,408,869 | 660,099 | 7,113,00 |
| Cash and cash equivalents at beginning of period | 1,704,131 | 202,335 | |
| Cash and cash equivalents at end of period | \$ 7,113,000 | \$ 862,434 | \$ 7,113,00 |
| 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 |

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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 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 United States Food and Drug Administration (the "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 doxorubicin and melphalan, chemotherapeutic agents, to treat malignant melanoma that has spread to the liver.

Note 2: Basis of Presentation

The accompanying financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended September 30, 2006 and 2005 and cumulative from inception (August 5, 1988) to September 30, 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: 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. Research and development costs and expenses includes \$338,539 and \$-0- of stock option compensation expense for the nine-months ended

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

September 30, 2006 and 2005, respectively. (See Note 5).

General and Administrative Expenses

General and administrative expenses include the Company's general and administrative operating expenses. Included in these expenses are \$166,743 and \$-0- of stock option compensation expense for the nine-months ended September 30, 2006 and 2005, respectively. (See Note 5). Also included in general and administrative expenses are approximately \$3.9 million of legal and other costs incurred in connection with the consent solicitation during the quarter ended September 30, 2006.

6.

Note 4: Stockholders' Equity

During the nine months ended September 30, 2006, the Company received net proceeds of \$6,388 (\$1.022 per share) upon the exercise of 1,250 of the Representative Unit Purchase Warrants that were issued to underwriters as part of the Company's public offering in 2003. In addition, 6,250 Representative's Common Stock Warrants were exercised and net proceeds of \$8,000 (\$1.28 per share) were received with an additional 6,250 shares of common stock being issued.

The Company received a net amount of \$204,900 upon the exercise of stock options for 80,000 shares during the nine months ended September 30, 2006. Of those options, 10,000 were exercised at a price of \$1.03 per share and 70,000 were exercised at a price of \$2.78.

During the nine months ended September 30, 2006, the Company received net proceeds of \$4,879,268 as 143,308 of the March 2004 Warrants were exercised, 927,115 of the November 2004 Warrants were exercised, 94,787 of the December 2004 warrants were exercised, and 429,218 of the November 2005 Warrants were exercised for which it has issued shares of its common stock.

The following table sets forth changes in stockholders' equity during the nine months ended September 30, 2006:

| | Common Stock, \$0.01 Par Value Issued and Outstanding | | Additional Paid in Capital | Deficit Dur Develop |
|---|--|-----------------|-------------------------------|---------------------------|
| | ----- No. of shares ----- | Amount ----- | | |
| Balance at December 31, 2005 | 18,849,653 | \$188,497 | \$38,244,566 | \$ (25,8 |
| Issuance of common stock in connection with the exercise of 2003 Representative's Unit Purchase Warrants | 6,250 | 63 | 6,325 | |
| Issuance of common stock in connection with the exercise of Representative's Common Stock | | | | |

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

| | | | | |
|--|------------|-----------|--------------|----------|
| Warrants | 6,250 | 63 | 7,937 | |
| Issuance of common stock in connection with the exercise of stock options | 80,000 | 800 | 204,100 | |
| Issuance of common stock in connection with the exercise of 2004 and 2005 Warrants | 1,594,428 | 15,944 | 4,863,324 | |
| Vesting of stock options | -- | -- | 505,282 | |
| Net loss for nine months ended September 30, 2006 | | | | (7,4 |
| | ----- | ----- | ----- | ----- |
| Balance at September 30, 2006 | 20,536,581 | \$205,367 | \$43,831,534 | \$ (33,2 |
| | ===== | ===== | ===== | ===== |

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

7.

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 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 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 did not have a 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

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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 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 a non cash compensation expense of \$505,282 on January 1, 2006 which is included in costs and expenses 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 nine-month period ended September 30, 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 nine months ended September 30, 2005 would have been increased to the pro forma amounts indicated as follows:

| | |
|--|----------------|
| Net loss, as reported | \$ (2,184,164) |
| Stock-based employee compensation expense included in net loss, net of related tax effects | 0 |

8.

| | |
|--|----------------|
| Stock-based employee compensation determined under the fair value based method, net of related tax effects | (80,097) |
| | ----- |
| Pro forma net loss | \$ (2,264,261) |
| | ===== |
| As reported | \$ (0.14) |
| Pro forma | (0.14) |

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,

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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.

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 2004 Stock Incentive Plan, became effective. Options granted under the Plans vest as determined by the Compensation and Stock Option Committee 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 nine-month period ended September 30, 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 | 10,000 | \$2.78 - \$3.59 | \$3.39 |
| Exercised | 80,000 | \$1.03 - \$2.78 | \$2.56 |
| | ----- | | |
| Outstanding at September 30, 2006 | 1,295,800 ===== | \$0.71 - \$3.59 | \$2.81 |

Note 6: Contingencies

The Company has had in effect since 2003 a plan that was approved by the Compensation and Stock Option Committee providing for payments to certain of its directors and officers in the event of a change in control (as defined) of Delcath occurs. A trust was formed the beneficiaries of which are the persons entitled to receive payments under this plan but no assets were transferred to the trust at that time. During the quarter ended September 30, 2006, the trust was partially funded with approximately \$3 million. The assets of the trust are subject to the claims of the Company's general creditors in the event of the Company's insolvency.

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

(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 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, the Company initiated a Phase I clinical study at The National Cancer Institute of the Delcath system for isolated liver perfusion using the chemotherapeutic agent, melphalan. The Phase I trial marked an expansion in the potential labeled usage beyond doxorubicin, the chemotherapeutic agent used in our initial clinical trials. Enrollment of new patients in the Phase I trial was completed in 2003.

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 currently recruiting sites worldwide.

During 2005, we commenced a Phase II multiple histology study of the Delcath drug delivery system for cancers related to the colon, breast, and lymph nodes using melphalan and patients are being enrolled and treated.

In 2006, 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

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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.

10.

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 or a substantial increase in sites for the Phase III human clinical trials occurs. 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 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 or, again, if a substantial increase in sites for the Phase III human clinical trials occurs. There can be no assurance that such working capital will be available on acceptable terms, if at all.

During the nine months ended September 30, 2006, the Company had exercised of previously issued options and warrants. Please see Note 4 to the September 30, 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 The National Cancer Institute 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 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 nine months ended September 30, 2006.

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

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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

11.

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

During the quarter ended September 30, 2006, the Company commenced two new lawsuits.

On August 4, 2006, the Company instituted a lawsuit against Robert Ladd, Laddcap Value Associates LLC and Laddcap Value Partners LP (collectively, the "Ladd Defendants") in the U.S. District Court for the District of Columbia. The lawsuit alleged that the Ladd Defendants had made a series of material misstatements and omissions in violation of the Securities Exchange Act of 1934 in its 13D filings, Valuation Proxy Solicitation and Schedule 14A Preliminary Proxy Statement for their proposed consent solicitation seeking to replace the Company's Board of Directors. The principal relief sought by the Company was an order: (a) enjoining the Ladd Defendants proposed consent solicitation until after a trial can be held on the merits; (b) mandating that the Ladd Defendants

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

publicly correct their misstatements and omissions following a trial on the merits; and (c) prohibiting the Ladd Defendants from making any further misstatements and omissions.

On October 8, 2006, the Company entered into a Settlement Agreement resolving all issues outstanding with the Ladd Defendants. The agreement provides for the immediate appointment of Mr. Robert B. Ladd, 48, Principal of Laddcap Value Partners, to the Delcath Board of Directors and one additional independent director to be mutually agreed upon by Laddcap and the Company. The Company issued 100,000 shares of common stock to Laddcap as partial reimbursement for its expenses associated with the Consent Solicitation. As part of the agreement, Laddcap is also permitted to increase its ownership in Delcath up to a maximum of 14.9% of Delcath's total outstanding common stock by purchasing additional shares of Delcath common stock directly and only from Delcath for a cash price equal to the 10 trading day average of the closing price of Delcath stock prior to the time that an additional purchase is made.

In conjunction with the resolution, Delcath has agreed to terminate its lawsuit against the Ladd Defendants relating to its claims under Sections 13(d) and 14(a) of the Securities Exchange Act of 1934 and Laddcap has agreed to end its attempt to remove the Delcath Board of Directors.

In addition, on August 4, 2006, the Company instituted a lawsuit against Jonathan Foltz by filing a complaint in the State of Connecticut Superior Court for the Judicial District of Stamford/Norwalk at Stamford. The complaint alleges that Mr. Foltz, the former Director of Operations of Delcath, has misappropriated various Delcath trade secrets and other proprietary information and has wrongly shared such protected information with

12.

other parties and has also used the information for his own personal gain. The complaint alleges that Mr. Foltz violated the Uniform Trade Secrets Act and the Unfair Trade Practices Act of Connecticut. The relief sought by the Company includes a temporary and permanent injunction, money damages, including punitive damages, and attorney's fees.

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

On July 21, 2006, the Company issued an aggregate of 52,711 shares of its Common Stock upon exercise of then outstanding Warrants to Purchase Shares of Common Stock dated November 27, 2005. The Company received an aggregate of \$206,100 upon such exercises. On July 27, 2006, the Company issued an aggregate of 94,787 shares of its Common Stock upon exercise of then outstanding Warrants to Purchase Shares of Common Stock dated December 8, 2004. The Company received an aggregate of \$309,006 upon such exercises. In August 2006, the Company issued an aggregate of 577,542 shares of its Common Stock upon exercise of then outstanding Warrants to Purchase Shares of Common Stock dated November 24, 2004. The Company received an aggregate of \$1,606,567 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

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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

During the quarter ended September 30, 2006, the Ladd Defendants commenced a solicitation of consents from the Company's stockholders seeking to remove all of the Company's directors and replacing them with nominees selected by the Ladd Defendants. The consent solicitation was terminated when the Company and the Ladd Defendants entered into a Settlement Agreement described herein under "Legal Proceedings." In addition, see the second paragraph of Note 3 to the Notes to Condensed Financial Statements included in Part I.

Item 5. Other Information

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

There has been no material change to the procedures by which security holders may recommend nominees for election to the Company's Board of Directors from the procedures described in the Company's proxy statement for its 2006 Annual Meeting of Stockholders.

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.

13.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DELCATH SYSTEMS, INC.
(Registrant)

November 14, 2006

/s/ PAUL M. FEINSTEIN

Edgar Filing: DELCATH SYSTEMS INC - Form 10QSB

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

14.