

DELCATH SYSTEMS INC  
Form 10-Q  
May 05, 2010

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, 2010.

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.)

810 Seventh Avenue, Suite 3505. New York, NY 10019

(Address of principal executive offices)

(212) 489-2100

(Registrant's telephone number, including area code)

600 Fifth Avenue, 23RD Floor  
New York, New York

(Former name or former address, if changed since last  
report.)

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

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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 May 4, 2010, 37,282,081 shares of the Company's common stock, \$0.01 par value were outstanding.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Index

|   | Page |
|---|------|
| Part I: FINANCIAL INFORMATION   | 1    |
| Item 1.   | 1    |
| Condensed Financial Statements (Unaudited)  | 1    |
| Management's Discussion and Analysis of Financial Condition and Results of Operations | 2    |
| Item 2.   | 2    |
| Item 3.   | 6    |
| Quantitative and Qualitative Disclosures about Market Risk                            | 6    |
| Item 4.   | 6    |
| Controls and Procedures   | 6    |
| PART II: OTHER INFORMATION  | 7    |
| Item 1.   | 7    |
| Legal Proceedings   | 7    |
| Item 1A.  | 7    |
| Risk Factors  | 7    |
| Item 2.   | 7    |
| Unregistered Sales of Equity Securities and Use of Proceeds                           | 7    |
| Item 3.   | 7    |
| Defaults upon Senior Securities   | 7    |
| Item 5.   | 7    |
| Other Information   | 7    |
| Item 6.   | 7    |
| Exhibits  | 7    |
| SIGNATURES  | 8    |

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

PART I:

FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Index to Financial Statements

|  | Page      |
|--|-----------|
| Condensed Balance Sheets<br>March 31, 2010 and December 31, 2009   | F-1       |
| Condensed Statements of Operations<br>for the Three Months Ended March 31, 2010 and 2009 and Cumulative from Inception (August 5,<br>1988) to March 31, 2010 | F-2       |
| Condensed Statements of Cash Flows<br>for the Three Months Ended March 31, 2010 and 2009 and Cumulative from Inception (August 5,<br>1988) to March 31, 2010 | F-3       |
| Notes to Condensed Financial Statements  | F-4 – F-8 |

DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Balance Sheets  
(Unaudited)

|  | March 31,<br>2010 | December<br>31,<br>2009 |
|--|-------------------|-------------------------|
| <b>Assets:</b>   |                   |                         |
| <b>Current assets</b>  |                   |                         |
| Cash and cash equivalents  | \$26,933,593      | \$35,486,319            |
| Investments – CDs  | 3,235,000         | –                       |
| Prepaid expenses and other assets  | 1,157,775         | 799,416                 |
| Total current assets   | 31,326,368        | 36,285,735              |
| <b>Property, plant and equipment</b>   |                   |                         |
| Furniture and fixtures   | \$55,692          | \$36,800                |
| Computers and equipment  | 104,617           | 78,063                  |
| Leasehold improvements   | 833,240           | 431,425                 |
|  | 993,549           | 546,288                 |
| Less: accumulated depreciation   | (85,578 )         | (24,982 )               |
| Property, plant and equipment, net   | 907,971           | 521,306                 |
| Total assets   | 32,234,339        | 36,807,041              |
| <b>Liabilities and Stockholders' Equity:</b>   |                   |                         |
| <b>Current liabilities</b>   |                   |                         |
| Accounts payable and accrued expenses  | \$1,266,019       | \$1,841,480             |
| Warrant liability  | 19,894,931        | 11,207,214              |
| Total current liabilities  | 21,160,950        | 13,048,694              |
| Deferred revenue   | 300,000           | –                       |
| Commitments and contingencies  | –                 | –                       |
| <b>Stockholders' equity</b>  |                   |                         |
| Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding   | –                 | –                       |
| Common stock, \$.01 par value; 70,000,000 shares authorized; 36,678,838 and 36,531,007 shares issued and 36,650,738 and 36,502,907 outstanding at March 31, 2010 and December 31, 2009, respectively | 366,888           | 362,231                 |
| Additional paid-in capital   | 94,011,294        | 92,835,174              |
| Deficit accumulated during the development stage   | (83,545,490)      | (69,371,755)            |
| Treasury stock, at cost; 28,100 shares at March 31, 2010 and December 31, 2009   | (51,103 )         | (51,103 )               |
| Accumulated other comprehensive loss   | (8,200 )          | (16,200 )               |
| Total stockholders' equity   | 10,773,389        | 23,758,347              |
| Total liabilities and stockholders' equity   | \$32,234,339      | \$36,807,041            |

See accompanying notes to condensed financial statements.

F-1

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Statements of Operations and Comprehensive Income

(Unaudited)

|  | Three Months Ended<br>March 31, |                | Cumulative<br>from<br>Inception<br>(Aug 5,<br>1988)<br>to<br>March 31,<br>2010 |
|--|---------------------------------|----------------|--|
|  | 2010                            | 2009           | 2010   |
| <b>Costs and expenses:</b>   |                                 |                |  |
| General and administrative expenses                                      | \$2,546,172                     | \$474,964      | \$29,223,976   |
| Research and development costs   | 2,941,110                       | 1,461,189      | 41,975,576   |
| Total costs and expenses   | \$5,487,282                     | \$1,936,153    | \$71,199,552   |
| Operating loss   | (5,487,282 )                    | (1,936,153 )   | (71,199,552)   |
| Change in fair value of warrant liability, net                           | (8,687,717 )                    | (561,778 )     | (13,434,952)   |
| Interest income  | 1,264                           | 50,761         | 2,861,845  |
| Other income   | -                               | 1,689          | (102,753 )   |
| Interest expense   | -                               | -              | (171,473 )   |
| Net loss   | (14,173,735 )                   | (2,445,481 )   | (82,046,885)   |
| Other comprehensive income (loss)  | 8,000                           | (3,000 )       | (8,200 )   |
| Total comprehensive loss   | \$(14,165,735)                  | \$(2,448,481 ) | \$(82,055,085)   |
| <b>Common share data:</b>  |                                 |                |  |
| Basic and diluted loss per share   | \$(0.39 )                       | \$(0.10 )      |  |
| <b>Weighted average number of shares<br/>of common stock outstanding</b> |                                 |                |  |
|  | 36,261,688                      | 25,355,254     |  |

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Statements of Cash Flows  
(Unaudited)

|  | Three Months Ended<br>March 31, |               | Cumulative<br>from<br>inception<br>(Aug. 5,<br>1988)<br>to March 31,<br>2010 |
|--|---------------------------------|---------------|--|
|  | 2010                            | 2009          |  |
| <b>Cash flows from operating activities:</b>                                       |                                 |               |  |
| Net loss   | \$(14,173,735)                  | \$(2,445,481) | \$(82,046,885)   |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                                 |               |  |
| Stock option compensation expense  | 633,135                         | 65,005        | 7,572,074  |
| Stock and warrant compensation expense   | 341,483                         | 40,333        | 2,222,177  |
| Depreciation expense   | 60,596                          | 1,465         | 120,339  |
| Loss on disposal of furniture and fixtures   | –                               | –             | 3,442  |
| Amortization of organization costs   | –                               | –             | 42,165   |
| Non-cash interest income   | (1,151 )                        | (45,452 )     | (9,055 )   |
| Warrant liability fair value adjustment  | 8,687,717                       | 561,778       | 13,434,952   |
| <b>Changes in assets and liabilities:</b>  |                                 |               |  |
| Decrease (increase) in prepaid expenses and other assets                           | (349,208 )                      | (23,103 )     | (1,118,624 )   |
| Increase (decrease) in accounts payable and accrued expenses                       | (575,461 )                      | (490,346 )    | 1,266,019  |
| Deferred revenue   | 300,000                         | –             | 300,000  |
| Net cash used in operating activities  | \$(5,076,624 )                  | \$(2,335,801) | \$(58,213,396)   |
| <b>Cash flows from investing activities:</b>                                       |                                 |               |  |
| Purchase of equipment or furniture and fixtures                                    | \$(447,261 )                    | \$–           | \$(1,031,953 )   |
| Purchase of short-term investments   | (3,235,000 )                    | –             | (44,646,452)   |
| Proceeds from sale of equipment  | –                               | –             | 200  |
| Purchase of marketable equity securities   | –                               | –             | (46,200 )  |
| Proceeds from maturities of short-term investments                                 | –                               | 200,710       | 41,419,356   |
| Organization costs   | –                               | –             | (42,165 )  |
| Net cash (used in) provided by investing activities                                | \$(3,682,261 )                  | \$200,710     | \$(4,347,214 )   |
| <b>Cash flows from financing activities:</b>                                       |                                 |               |  |
| Net proceeds from sale of stock and exercise of stock options and warrants         | \$206,159                       | \$–           | \$88,339,877   |
| Repurchases of common stock  | –                               | –             | (51,103 )  |
| Dividends paid on preferred stock  | –                               | –             | (499,535 )   |
| Proceeds from short-term borrowings  | –                               | –             | 1,704,964  |
| Net cash provided by financing activities  | \$206,159                       | \$–           | \$89,494,203   |
| (Decrease) increase in cash and cash equivalents                                   | (8,552,726 )                    | (2,135,091)   | 26,933,593   |
| Cash and cash equivalents at beginning of period                                   | 35,486,319                      | 6,939,233     | –  |
| Cash and cash equivalents at end of period   | \$26,933,593                    | \$4,804,142   | \$26,933,593   |
| <b>Supplemental cash flow information:</b>   |                                 |               |  |
| Cash paid for interest   | –                               | –             | 171,473  |
| <b>Supplemental non-cash activities:</b>   |                                 |               |  |
| Cashless exercise of stock options   | \$184,000                       | \$–           | \$544,116  |



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|  |   |   |           |
|--|---|---|-----------|
| Conversion of debt to common stock                 | – | – | 1,704,964 |
| Common stock issued for preferred stock dividends  | – | – | 999,070   |
| Conversion of preferred stock to common stock      | – | – | 24,167    |
| Common stock issued as compensation for stock sale | – | – | 510,000   |
| Fair value of warrants issued                      | – | – | 6,459,979 |

See accompanying notes to condensed financial statements.

F-3

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Notes to Condensed Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. (the “Company”), a development stage, oncology focused, specialty pharmaceutical and medical device company, is developing the Delcath Percutaneous Hepatic Perfusion (PHP) System (the “System”), an investigational system which is comprised of the chemotherapeutic agent melphalan combined with a proprietary administration system. The System is designed to provide a regionalized approach for the treatment of unresectable hepatic malignancies in which an ultra-high dose of anti-cancer drug is administered to the liver via the hepatic artery and venous effluent from the liver is collected and filtered using a percutaneously placed catheter and an extracorporeal filtration system. Significantly higher doses of anti-cancer drugs can therefore be delivered to a patient's liver while minimizing entry of the drugs into the rest of the patient's circulation. This isolation limits toxicities which result from systemic chemotherapy treatments and allows for infusion of doses exceeding those of systemic or intra-arterial administration. The Delcath PHP System is not currently approved for marketing by the FDA or any other foreign regulatory agency and has not been determined to be safe and effective for this intended use. We believe that the Delcath PHP System is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with the Delcath PHP System is for the treatment of primary and secondary cancers of the liver. We recently released top-line data for our Phase III trial and are currently conducting a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers.

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”) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The unaudited interim condensed financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company’s results of operations, financial position and cash flows for the interim periods ended March 31, 2010 and 2009, and cumulative from inception (August 5, 1988) to March 31, 2010. In connection with the preparation of the condensed financial statements and in accordance with the recently issued Financial Accounting Standards Board Accounting Standards Codification (“FASB ASC”) 855-10, the Company evaluated subsequent events.

The results of operations and cash flows 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, 2009, which are contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission (the “SEC”) on February 26, 2010 (the “2009 Form 10-K”).

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 salaries and related expenses for our executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and

certain general legal activities.

#### Deferred Revenue Recognition

Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. This agreement is discussed further in Note 7 to the Company's unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q. The Company will amortize deferred revenue over the expected obligation period of the agreement.

#### Investments

The Company invests the majority of its cash in money market funds and certificates of deposit. The money market funds are accounted for based on the guidance for fair value measurements and are discussed further in Note 6 to the Company's unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q. The Company's certificates of deposit are accounted for based on the guidance for investments, which requires securities to be categorized as either trading, available-for-sale or held-to-maturity. The certificates of deposit are classified as held-to-maturity and, as such, are carried at amortized cost.

F-4

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## Note 3: Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standard Update (“ASU”) No. 2009-13, which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services separately rather than as a combined unit and modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. The ASU significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. The ASU will be effective for the first annual reporting period beginning on or after June 15, 2010. The Company is currently evaluating the impact this update may have on its financial statements.

## Note 4: Investment in Marketable Equity Securities

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc., (“AEMD”) a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of that agreement, the Company received 100,000 shares of restricted common stock of AEMD. The Company allocated \$46,200 of the cost of the agreement to the fair value of the common stock acquired, using the closing stock price at the date of the agreement. The investment is classified as an available-for-sale security and had a fair value on March 31, 2010 of \$38,000 which included a gross unrealized loss of \$8,200, which is included as a component of comprehensive loss.

## Note 5: Stock Option Plans

The Company established the 2000 Stock Option Plan, the 2001 Stock Option Plan, the 2004 Stock Incentive Plan, and the 2009 Stock Incentive Plan (collectively, the “Plans”) under which 300,000, 750,000, 3,000,000, and 2,000,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. 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 awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

During 2000, 2001, 2004 and 2009, respectively, the 2000 and 2001 Stock Option Plans and the 2004 and 2009 Stock Incentive Plans became effective. Options granted under the Plans vest as determined by the Company’s Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the three month period ended March 31, 2010 is as follows:

|                                  | The Plans     |                          |                                 |   |
|----------------------------------|---------------|--------------------------|---------------------------------|---|
|                                  | Stock Options | Exercise Price per Share | Weighted Average Exercise Price | Weighted Average Remaining Life (Years) |
| Outstanding at December 31, 2009 | 3,345,000     | \$6.18                   | \$3.72                          | 6.58                                    |
| Granted                          | 116,000       | \$5.28-8.10              | 6.19                            | -                                       |
| Expired                          | -             | -                        | -                               | -                                       |
| Exercised                        | 70,000        | \$3.45                   | \$2.41                          | -                                       |
| Outstanding at March 31, 2010    | 3,391,000     | \$8.10                   | \$3.83                          | 6.52                                    |

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For the three months ended March 31, 2010, the Company recognized compensation expense of \$589,498 relating to options granted in previous years and \$43,637 relating to options granted during 2010. For the three months ended March 31, 2009, the Company recognized compensation expense of \$65,005.

The Company uses an option pricing model to determine the fair value of stock options on the date of grant. The Company has expensed its share-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The assumptions used in the option pricing model are as follows:

|                             | Three Months Ended March 31, |           |
|-----------------------------|------------------------------|-----------|
|                             | 2010                         | 2009      |
| Dividend yield              | None                         | None      |
|                             | 73.10% -                     |           |
| Expected volatility         | 75.04                        | % 74.83 % |
| Weighted average volatility | 74.15                        | % 74.83 % |
|                             | 2.66% -                      |           |
| Risk-free interest rates    | 3.00                         | % 1.01 %  |
| Expected life (in years)    | 5.0 – 6.0                    | 2.5       |

## Note 6: Assets and Liabilities Measured at Fair Value

## Derivative financial instruments

The Company has allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in FASB ASC 820-10-35. There are six inputs: the closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on our historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (820-10-35-40). The riskless rate of return is a Level 2 input as defined in 820-10-35-48, while the historical volatility is a Level 3 input as defined in FASB ASC 820-10-55-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of \$3 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants, resulting in net proceeds of \$467,559. The fair value of the 2009 Warrants on June 15, 2009 was determined using an option pricing model model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the warrants (June 2014). The 2009 Warrants are exercisable at \$3.60 per share and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of \$13,303,267 in this transaction. The Company allocated \$4,269,000 of the total proceeds to 2007 Warrants. The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrants agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 2,345,628 warrants outstanding. The shares were issued pursuant to an effective registration statement on Form S-3.

The \$2,190,979 in proceeds allocated to the 2009 Warrants and the \$4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2010, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument expense of \$8,687,717. The resulting warrant liability totaled \$19,894,931 at March 31, 2010. Management believes that the possibility of an actual cash settlement with a warrant holder is quite remote, and expects that the Warrants will either be exercised or expire worthless, at which point the then existing warrant liability will be credited to stockholders' equity. The fair value of the Warrants at March 31, 2010 was determined by using an option pricing model assuming a risk free interest rate of 2.17% for the 2009 Warrants

and 1.30% for the 2007 Warrants, volatility of 74.26% for the 2009 Warrants and 90.79% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

#### Marketable Equity Securities

The Company owns 100,000 shares of common stock of Aethlon Medical, Inc. ("AEMD"). At March 31, 2010, the valuation of such stock was determined utilizing the current quoted market price of AEMD. The Company has determined that the quoted market price is readily observable in an active market and, as a result, the instrument was classified within Level 1 of the fair-value hierarchy.

#### Money Market Funds

Cash and cash equivalents includes a money market account valued at \$25,778,701.

F-6

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The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2010, aggregated by the level in the fair value hierarchy within which those measurements fall:

Assets and Liabilities Measured at Fair Value on a Recurring Basis at March 31, 2010

|                              | Level 1             | Level 2    | Level 3             | Balance at March 31, 2010 |
|------------------------------|---------------------|------------|---------------------|---------------------------|
| <b>Assets</b>                |                     |            |                     |                           |
| Marketable equity securities | \$38,000            | \$-        | \$-                 | \$38,000                  |
| Money market funds           | 25,778,701          | -          | -                   | 25,778,701                |
| <b>Total Assets</b>          | <b>\$25,816,701</b> | <b>\$-</b> | <b>\$-</b>          | <b>\$25,816,701</b>       |
| <b>Liabilities</b>           |                     |            |                     |                           |
| Warrant liability            | \$-                 | \$-        | \$19,894,931        | \$19,894,931              |
| <b>Total Liabilities</b>     | <b>\$-</b>          | <b>\$-</b> | <b>\$19,894,931</b> | <b>\$19,894,931</b>       |

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

|                                   | Warrant Liability |
|-----------------------------------|-------------------|
| Beginning balance                 | \$ 11,207,214     |
| Total losses included in earnings | 8,687,717         |
| Ending balance                    | \$ 19,894,931     |

Note 7: Research and Distribution Agreement

On February 9, 2010, the Company entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd. (the "Research and Distribution Agreement"). The Research and Distribution Agreement grants Chi-Fu the exclusive right to promote, market, sell and distribute the Delcath PHP System in Taiwan for hepatic malignancies and infectious disease upon Taiwan Food and Drug Administration ("TFDA") approval, and for any other TFDA approved indications for treatment using the Delcath PHP System (collectively, the "Field of Use"). The Research and Distribution Agreement also grants Chi-Fu the right to extend its exclusive distribution rights to Singapore, subject to the satisfaction of certain conditions.

Pursuant to the Research and Distribution Agreement Chi-Fu will plan, fund and manage clinical studies of the Delcath PHP System in the Field of Use with initial focus on the treatment of hepatic malignancies at not less than two and up to four sites in Taiwan, and will promptly file for TFDA approval of the Delcath PHP System for as many indications of use as possible, promptly following Delcath's receipt of U.S. Food and Drug Administration ("FDA") approval of the Delcath PHP System. Chi-Fu's exclusive right to market, sell and distribute the Delcath PHP System in Taiwan in the Field of Use will begin on the date TFDA approval of the Delcath PHP System is granted and will continue for the term of the Research and Distribution Agreement. Beginning on the first day of the month in which TFDA approval is obtained, Chi-Fu is obligated to purchase a minimum number of Delcath PHP Systems annually during the term of the Research and Distribution Agreement; with such minimum purchase requirements to increase annually over the remaining term of the Research and Distribution Agreement. The Research and Distribution Agreement requires Chi-Fu to pay Delcath \$1 million in milestone payments, comprised of \$300,000 paid upon execution of the Research and Distribution Agreement and the balance in two installments, upon receipt of the CE Mark and upon receipt of FDA approval.

The term of the Research and Distribution Agreement commenced on February 9, 2010 and will continue for five (5) years from the first day of the month in which TFDA approval is obtained, following which the Research and



Distribution Agreement will automatically renew for an additional five (5) years provided Chi-Fu has met all of its obligations under the Research and Distribution Agreement, including its minimum purchase requirements.

Note 8: Income Taxes

As discussed in Note 4 to the Company's audited financial statements contained in the 2009 Annual Report on 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 its balance sheet.

F-7

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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 United States Internal Revenue Service (the "IRS") or any states in connection with income taxes. The periods from December 31, 2003 to December 31, 2009 remain open to examination by the IRS and state authorities. Also note that for federal and state purposes, the tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

For the quarter ended March 31, 2010, the Company recorded a state income tax benefit of \$62,500 in the Statement of Operations. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to \$250,000 per year.

#### Note 9: Subsequent Events

On April 21, 2010, the Company issued a press release announcing that its Phase III National Cancer Institute (NCI)-led multi-center clinical trial has successfully met the study's primary endpoint of extended hepatic progression-free survival (hPFS) in patients with melanoma metastases to the liver based on an independently corroborated intent-to-treat analysis. Comparing treatment with the Delcath PHP System with melphalan to Best Alternative Care (BAC), based on independent core lab review of patient scans, the statistical analysis revealed that the PHP patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the BAC arm ( $p=0.001$ ). This reflects a 144-day prolongation of hPFS over that of BAC control arm, with less than half the risk of progression and/or death in the PHP group compared to the BAC group (Hazard Ratio = 0.46).

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim condensed financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the year ended December 31, 2009 included in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC to provide an understanding of our results of operations, financial condition and cash flows.

### Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terms often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Exchange Act"). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in the Company's Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in this report under "risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
  - the results and timing of our clinical trials and the commencement of future clinical trials; and
  - submission and timing of applications for regulatory approval.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements contained in this Annual Report on Form 10-Q, which speak only as of the date of this report. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Delcath® is a registered trademark of Delcath Systems, Inc. and The Delcath PHP System™ is a trademark of Delcath Systems, Inc. All rights reserved.

### Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Financial Statements of this report and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K.

We are developing the Delcath Percutaneous Hepatic Perfusion System, or the Delcath PHP System, an investigational system which is comprised of the chemotherapeutic agent melphalan combined with a proprietary administration system. The System is designed to provide a regionalized approach for the treatment of unresectable hepatic malignancies in which an ultra-high dose of anti-cancer drug is administered to the liver via the hepatic artery

and venous effluent from the liver is collected and filtered using a percutaneously placed catheter and an extracorporeal filtration system. Significantly higher doses of anti-cancer drugs can therefore be delivered to a patient's liver while minimizing entry of the drugs into the rest of the patient's circulation. This isolation limits toxicities which result from systemic chemotherapy treatments and allows for infusion of doses exceeding those of systemic or intra-arterial administration. The Delcath PHP System is not currently approved for marketing by the FDA or any other foreign regulatory agency and has not been determined to be safe and effective for this intended use. We believe that the Delcath PHP System is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with our System is for the treatment of primary and secondary cancers of the liver. We recently released top-line data for our Phase III trial and are currently conducting a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers.

The System is a disposable kit consisting of various catheters, filters, and a tubing circuit used during cancer treatment to isolate the liver from the patient's general circulatory system. The System allows for ultra-high doses of chemotherapy agents to be directed at a patient's liver while at the same time limiting the exposure of healthy tissue and organs to the harmful effects of those chemotherapeutic agents. By providing higher dosing of chemotherapy agents than would otherwise be possible through conventional chemotherapy, we believe that treatment with the System has the potential to be more effective than conventional treatment at killing cancer cells and preventing new cancer cell formation.

We began enrollment of our Phase III clinical trial to support a marketing registration application for use of the System with melphalan, a chemotherapy agent, for the treatment of metastatic melanoma that has spread to the liver. The trial is being conducted under an FDA Special Protocol Assessment (“SPA”) with the National Cancer Institute (the “NCI”) serving as the coordinating center. Until April 2008, the NCI was the sole participating center in the trial. Since then, we have negotiated and entered into research relationships with eleven centers as part of this trial, bringing the total number of centers to twelve:

2008, 2nd Quarter  
University of Maryland  
Medical Center  
St. Luke’s Cancer Center  
Albany Medical Center  
Atlantic Melanoma  
Center of Atlantic Health  
University of Texas  
Medical Branch  
2008, 3rd Quarter  
Swedish Medical Center  
John Wayne Cancer  
Institute  
Providence Health  
Systems  
Moffitt Cancer Center  
2008, 4th Quarter  
University of Pittsburgh  
Medical Center  
2009, 1st Quarter  
Ohio State University  
Comprehensive Cancer  
Center

Either a participating center’s Institutional Review Board (“IRB”) or the Western Institutional Review Board (“WIRB”) has approved our protocol. The WIRB, which provides review services for more than 100 institutions (academic centers, hospitals, networks and in-house biotech research) in all 50 states and internationally, helped accelerate the internal review process at a number of the hospitals participating in the study. The trial reached full enrollment in October 2009. The Company expects expenses related to the trial to continue through 2010. In 2004, we began a multi-arm Phase II clinical trial for the use of the Delcath PHP System with melphalan in the treatment of hepatocellular carcinomas as well as neuroendocrine and adenocarcinoma cancers that have spread to the liver. In 2007, an additional arm was added to the Phase II clinical trial to treat patients with metastatic melanoma that has spread to the liver who have received prior regional treatment with melphalan and did not qualify for inclusion in the Phase III clinical trial. Based on promising initial clinical results, we focused our efforts on enrolling patients for the treatment of metastatic neuroendocrine tumors. That arm of the clinical trial has 25 patients enrolled.

The successful development of the Delcath PHP System is highly uncertain, and development costs and timelines can vary significantly and are difficult to accurately predict. Various statutes and regulations also impact the manufacturing, safety, labeling, storage, record keeping and marketing of our system. The lengthy process of completing clinical trials, seeking FDA approval and subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To date, we have not received approval for the sale of our system in any market and, therefore, have not generated any revenues. The Delcath PHP System has not yet been

approved by the FDA and may not be marketed in the United States without FDA approval.

Our expenses generally include costs for clinical studies, securing patents, regulatory activities, manufacturing, personnel, rent for our facilities, and general corporate and working capital, including general and administrative expenses. Because we have no FDA-approved product and no commercial sales, we will continue to be dependent upon existing cash, the sale of equity or debt securities, or establishing strategic alliances with appropriate partners to fund future activities. We cannot be assured that we will obtain FDA or other foreign approvals for our Delcath PHP System, that we will have, or could raise, sufficient financial resources to sustain our operations pending FDA or other foreign approvals, or that, if and when the required approvals are obtained, there will be a market for our product.

We expect that the amount of capital required for operations including preparation of the Company's submission to the FDA, operations at the manufacturing facility in upstate New York, and efforts to commercialize the Delcath PHP System will continue to increase over the coming months. We believe that we have sufficient capital for operations through 2010.

We are a development stage company, and since our inception we have raised approximately \$88.3 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses over the year.

## Results of Operations

### Three Months Ended March 31, 2010 and March 31, 2009

We have operated at a loss for our entire history. We had a net loss for the three months ended March 31, 2010, of \$14.2 million, which is an \$11.7 million increase in the net loss for the same period in 2009. The increase in net loss is due to an \$8.1 million increase in derivative instrument expense related to the Warrants, as well as an increase of \$3.6 million in total costs, which is primarily due to our recent hiring and our efforts to prepare for submission to the FDA. During the first quarter of 2009 we had seven full-time employees. At the end of the first quarter of 2010, we had 24 full-time employees and have expanded nearly every department throughout the Company. We anticipate this trend to continue throughout 2010.

General and administrative expenses increased by \$2 million, from \$475,000 during the three months ended March 31, 2009 to \$2.5 million for the three months ended March 31, 2010. With full enrollment of the Phase III clinical trial, the Company has begun taking steps to transition from a development stage company focused solely on research and development activities to a commercial enterprise with staff dedicated to commercializing the Delcath PHP System. The increase in the Company's general and administrative expenses is commensurate with these commercialization efforts. A significant portion of this increase is related to our recent hiring to expand our Marketing and Sales, Finance, and Manufacturing departments.

For the three months ended March 31, 2010, research and development expenses increased by 101.3%, from \$1.5 million during the first quarter of 2009 to \$2.9 million, an increase of \$1.4 million. Our recent hiring has also contributed to a marked increase in research and development expenses. Our facility in Queensbury is now operational and we have expanded both our Research and Development and Regulatory and Quality Assurance departments. Additionally, we have focused substantial efforts to completing our submission for FDA approval of the Delcath PHP System.

Interest income is from our money market account and certificates of deposit. During the three months ended March 31, 2010, the Company had interest income of \$1,264, as compared to \$50,761 for the same period in 2009. This decrease is principally due to market conditions which continue to yield a lower percentage of return than in previous years.

### Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we anticipate that losses will continue for the foreseeable future. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including our ongoing Phase II and Phase III clinical trials; 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. As we seek FDA and foreign approvals and commence marketing and manufacturing of our product we expect that our capital expenditures will increase significantly.

Nearly all of our available funds are invested in money market accounts and certificates of deposit. At March 31, 2010, we had cash and cash equivalents of \$26.9 million, as compared to \$35.5 million at December 31, 2009. Cash equivalents includes \$996,000 in certificates of deposit. In addition, the Company holds \$3,235,000 in certificates of deposit not classified as cash equivalents.

During the three months ended March 31, 2010, we used \$5.1 million of cash in our operating activities. This amount compares to \$2.3 million used in our operating activities during the comparable three month period in 2009. The increase of \$2.8 million, or 117.3%, is due to the recent personnel additions discussed above, our efforts to focus on preparing our submission to the FDA, and our preparations to commercialize the System. We expect that our cash allocated to operating activities will continue to increase as we aggressively move towards fully staffing our facility in upstate New York and continuing to navigate the extensive FDA approval process. We believe we have sufficient capital to fund our operating activities through 2010.

At March 31, 2010, the Company's accumulated deficit was approximately \$83.5 million. Because our business does not generate any positive cash flow from operating activities, we will need to continue raising additional capital in order to develop our product beyond the current clinical trials or to fund development efforts relating to new products. We believe that we could raise additional capital in the event that we find it in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when we need it, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from those planned because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

4

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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 along with our registered direct offering in 2007 and a public offering in November 2009. Please see the detailed discussion of our various sales of securities described in Note 3 to the Company's audited financial statements contained in the 2009 Annual Report on Form 10-K.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of \$3 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants, resulting in net proceeds of \$467,559 allocated to the common stock. The fair value of the 2009 Warrants on June 15, 2009 was determined by using an option pricing model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the warrants (June 2014). The 2009 Warrants are exercisable at \$3.60 per share and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

In March 2010, the Company filed a registration statement on Form S-3, which will allow the Company to offer and sell, from time to time in one or more offerings up to \$100,000,000 of common stock, preferred stock, stock purchase contracts, warrants and debt securities as it deems prudent or necessary to raise capital at a later date. The registration statement became effective April 13, 2010 (333-165677). The \$100,000,000 of securities registered includes \$24,810,000 of securities registered pursuant to Registration Statement No. 333-1559913 initially filed in June, 2009. The Company intends to use the net proceeds from any future offerings under the registration statement for general corporate purposes, including, but not limited to, funding its clinical trials, capital expenditures, working capital, repayment of debt and investments.

#### Critical Accounting Estimates

The Company's financial statements have been prepared in accordance with 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 2009 Annual Report on 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.

Additionally, the Company devotes substantial resources to clinical trials and other research and development activities related to obtaining FDA and other approvals for the Delcath PHP System, the cost of which is required to be charged to expense as incurred. This further limits our 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 FASB ASC 740 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. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, 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). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

On January 1, 2008, the Company adopted FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. FASB ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances. The adoption of FASB ASC 820 did not have a material effect on the carrying values of the Company's assets.

FASB ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, FASB ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to

5

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access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 6 to the Company's condensed financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under FASB ASC 820.

### Item 3. Quantitative and Qualitative Disclosures about Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the value of its investments. However, 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 fair value of the Company's investment portfolio or related income.

In January 2008, the Company entered into a research and development agreement with Aethlon Medical, Inc. ("AEMD"), a publicly traded company whose securities are quoted on the Over the Counter Bulletin Board. As part of that agreement, the Company received 100,000 shares of restricted common stock of AEMD. The Company allocated \$46,200 of the cost of the agreement to the fair value of the common stock acquired. The investment is classified as an available for sale security and had a fair value on March 31, 2010 of \$38,000, which included a gross unrealized loss of \$8,200, which is included as a component of comprehensive loss.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") in a subscription agreement with a single investor. The Company received gross proceeds of \$3 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2,190,979 to the 2009 Warrants, resulting in net proceeds of \$467,559 allocated to the common stock. The fair value of the 2009 Warrants on June 15, 2009 was determined by using an option pricing model assuming a risk free interest rate of 2.75%, volatility of 72.93% and an expected life equal to the contractual life of the 2009 Warrants (June 2014). The 2009 Warrants are exercisable at \$3.60 per share and have a five-year term.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of \$13,303,267 in this transaction. The Company allocated \$4,269,000 of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 2,523,834 warrants outstanding.

The \$2,190,979 in proceeds allocated to the 2009 Warrants and the \$4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to

mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2010, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument expense of \$8,687,717. The resulting warrant liability totaled \$19,894,931 at March 31, 2010. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing warrant liability will be credited to stockholders' equity. The fair value of the Warrants at March 31, 2010 was determined by using an option pricing model assuming a risk free interest rate of 2.17% for the 2009 Warrants and 1.30% for the 2007 Warrants, volatility of 74.26% for the 2009 Warrants and 90.79% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

#### Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of March 31, 2010 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

There were no changes to our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II:

OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Our 2009 Form 10-K, in Part 1, Item 1A. "Risk Factors," contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition. There have been no material changes in these risk factors since such disclosure.

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

On January 8, 2010, the Company withheld 15,394 shares of Delcath common stock that were the subject of a restricted stock award to satisfy the grantee's tax withholding obligations incurred in connection with the vesting of restricted stock, the per share value assigned to the shares of common stock withheld was \$5.45 per share.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 5. Other Information

On May 4, 2010, the Company entered into an amended and restated supply agreement with B. Braun Medical Inc. ("B.Braun Medical"), which amends, restates and replaces in its entirety the supply agreement dated January 11, 2010 between the Company and B.Braun Medical (the "Amended and Restated Supply Agreement"), and pursuant to which B. Braun Medical has agreed to supply the Company with double balloon catheters and double balloon catheter accessory packs, to sell the Company certain tooling and related equipment for the manufacturing of such products, and to provide the Company with certain technical and design assistance. A copy of the Amended and Restated Supply Agreement is attached as Exhibit 10.7 to this Quarterly Report on Form 10-Q.

Item 6. Exhibits

Exhibit

| Exhibit No. | Description  |
|-------------|--|
| 10.1        | Lease Agreement, dated as of February 5, 2010, by and between the Company and SLG 810 Seventh Lessee LLC.  |
| 10.2        | * Amendment No. 1. to the Form of Employee Stock Option Grant Letter, amended as of March 11, 2010, by and between the Company and Eamonn P. Hobbs |
| 10.3        | * Employee Stock Option Grant Letter by and between the Company and Eamonn P. Hobbs, Grant Date January 4, 2010                                    |
| 10.4        | * Form of Non-Statutory Stock Option Grant Letter  |
| 10.5        | * Form of Restricted Stock Agreement   |
| 10.6        | †  |

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Research and Distribution Agreement, dated as of February 9, 2010, by and between the Company and Chifu Trading Co., Ltd.

- 10.7 Amended and Restated Supply Agreement, dated May 4, 2010, by and between the Company and B. Braun Medical, Inc.
- 31.1 Certification by Principal executive officer Pursuant to Rule 13a-14(a).
- 31.2 Certification by Principal financial officer Pursuant to Rule 13a-14(a).
- 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 Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Secretary of the Securities Exchange Act of 1934, as amended.

\* Indicates management contract or compensatory plan or arrangement.

SIGNATURES

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

May 5, 2010

DELCATH SYSTEMS, INC.  
(Registrant)  
/s/David A. McDonald

David A. McDonald  
Chief Financial Officer  
(Principal Financial Officer)

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| 31.1        | Certification by Principal executive officer Pursuant to Rule 13a-14(a).  |
| 31.2        | Certification by Principal financial officer Pursuant to Rule 13a-14(a).  |
| 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 Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

\* Indicates management contract or compensatory plan or arrangement.





