

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

December 29, 2009

#### Via U.S. Mail and Facsimile

David A. McDonald Chief Financial Officer Delcath Systems, Inc. 600 Fifth Avenue, 23rd Floor New York, NY 10020

Re: Delcath Systems, Inc.

Form 10-K for the fiscal year ended December 31, 2008

Filed March 3, 2009

Form 10-Q for the fiscal quarter ended September 30, 2009

File No. 001-16133

#### Dear Mr. McDonald:

We have reviewed your filings and have the following comments. Where indicated, we think you should revise your future filings in response to these comments. If you disagree, we will consider your explanation as to why our comments are inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filings. We look forward to working with you in these respects. We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

## Form 10-K for the fiscal year December 31, 2008

# Item 1. Business, page 1

#### The Liver Cancer Market, page 2

1. We note from your disclosure on page 6 under "Our Clinical Trials" that you are currently pursuing FDA pre-market approval for the administration of melphalan with your system to treat patients suffering from metastatic melanoma that has spread to the liver. If known to you, and you believe such data is reliable, please indicate in your future filings the size of this market; i.e., the number of patients in the U.S. who could potentially be treated with your system and melphalan and that are suffering from metastatic melanoma that has spread to the liver. Expand your risk factor which currently appears at the top of page 12 as appropriate in your future filings.

#### Our Clinical Trials, page 5

2. If such data is available to you, please disclose is your future filing whether the side-effects experienced by patients who have received treatment using your system are more or less severe, or comparable, as compared to the side-effects experienced by patients who have received chemotherapy treatments using conventional intravenous deliver methods at lower dosages. For example, while it is clear that your system is capable of removing 85% of the higher dosages of chemotherapy agents you have tested, it is not clear whether 15% of the higher dosages that remain in the circulatory system is less than the chemotherapy agents that remain in a patient's circulatory system that have received lower dosages and would therefore cause less side-effects.

#### Our Clinical Trial and Agreement with the National Cancer Institute (NCI), page 6

3. We refer to the disclosure on pages 6 and F-20 of your Cooperative Research and Development Agreement with the National Cancer Institute. Please tell us where you filed as an exhibit your agreement with the National Cancer Institute.

# Research for Hepatitis Treatment, page 7

4. In your future filings, please clarify whether you anticipate that the use of your system for treating viral hepatitis would be limited to treating patients with chronic viral hepatitis or would also include those with active, but acute, forms of those diseases.

# Item 1A. Risk Factors, page 11

5. We note that you have a significant number of outstanding options and warrants, and that some of the warrants appear to have "ratchet down" provisions. In your future filings, if then material, please describe the potential dilutive effects of your outstanding options and warrants.

## <u>Item 11. Executive Compensation Directors, page 60</u>

In future filings, replace vague disclosure under "Compensation Discussion and 6. Analysis" that you have incorporated by reference from your proxy statement with meaningful information that investors can use to evaluate the compensation program for all of your named executive officers. For example, we note the disclosure on page 16 of the proxy statement that Messrs. Rifkin and Feinstein are named executive officers; however, you do not otherwise mention them in your "Compensation Discussion and Analysis." You should provide an analysis of how the compensation committee arrived at each particular level and form of compensation. For example, we note the references on pages 13 and 14 of the proxy statement to "performance" in determining certain elements of compensation. Disclose the elements of performance, both quantitative and qualitative, that the committee considered in its evaluation, and, if applicable, how they were weighted and factored into compensation decisions. As another example, we note you refer on pages 13 and 14 to "salaries paid in the marketplace to executives with similar responsibilities," "marketplace factors" and the "need to maintain a competitive total compensation value appropriate to each executive officer," however, you did not provide discussion and analysis of how the committee considered each of these factor in arriving at the amounts paid to each named executive officers.

# Form 10-Q for the quarterly period ended September 30, 2009

# <u>Item 1. Condensed Financial Statements (Unaudited)</u>

# Note 8. Assets and Liabilities Measured at Fair Value, page F-10

7. We reference the disclosure that the valuation of warrant derivative liability was classified within Level 2 of the fair-value hierarchy. Please tell us how you determined that the inputs were readily observable and how you considered that the inputs to the Black-Scholes pricing model would be considered Level 3. Please refer to FASB ASC 820-10-55 and 820-10-35-39 through 55.

# Item 4. Controls and Procedures, page 10

8. Please revise future filings to disclose any change in your internal control over financial reporting that occurred during your last fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting. Refer to Item 308(c) of Regulation S-K.

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As appropriate, please respond to these comments within 10 business days or tell us when you will provide us with a response. Please furnish a cover letter with your response that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes all information required under the Securities Exchange Act of 1934 and that they have provided all information investors require for an informed investment decision. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

In connection with responding to our comments, please provide, in writing, a statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in our review of your filing or in response to our comments on your filing.

You may contact Kristin Lochhead at (202) 551-3664 or Brian Cascio, Reviewing Accountant, at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Tom Jones at (202) 551-3602 or me at (202) 551-3635 if you have any other questions.

Sincerely,

Tim Buchmiller Senior Attorney