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

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): July 19, 2011 (July 14, 2011)

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

810 Seventh Avenue, Suite 3505, New York, New York, 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On July 14, 2011, Delcath Systems, Inc. (the "Company") entered into an underwriting agreement, dated July 14, 2011 (the "Underwriting Agreement") with Jefferies & Company, Inc. (the "Underwriter"). The Underwriting Agreement provides for the sale to the Underwriter of up to 5,750,000 shares of the Company's common stock, par value $0.01 per share, at a price to the Underwriter of $4.75 per share, including an overallotment option of 750,000 shares (the "Offering"). The shares are being offered and sold under a prospectus supplement filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 424(b) of the Securities Act of 1933, as amended, (the "Securities Act") in connection with an offering pursuant to the Company's shelf registration statement on Form S-3 (File Number 333-165677) (the "Registration Statement"). The Offering is expected to close on July 20, 2011.

The foregoing description of the Underwriting Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Underwriting Agreement, which is filed as Exhibit 1.1 hereto and incorporated herein by reference.

Item 8.01. Other Events.

In connection with the Offering, the Company provided certain information to investors in the prospectus supplement. A copy of this information is filed as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
1.1	Underwriting Agreement, dated July 14, 2011, between Delcath Systems, Inc. and Jefferies & Company, Inc.
99.1	Delcath Systems, Inc. Investor Information

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 hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: July 19, 2011

By: /s/ David A. McDonald
Name: David A. McDonald
Title: Chief Financial Officer

EXHIBIT INDEX

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Exhibit 1.1

EXECUTION COPY

5,000,000 Shares

Delcath Systems, Inc.

Common Stock

UNDERWRITING AGREEMENT

July 14, 2011

JEFFERIES & COMPANY, INC.
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

Introductory. Delcath Systems, Inc., a Delaware corporation (the "**Company**"), proposes to issue and sell to Jefferies & Company, Inc. ("**Jefferies**" or the "**Underwriter**") an aggregate of 5,000,000 shares of its common stock, par value $0.01 per share (the "**Shares**"). The 5,000,000 Shares to be sold by the Company are called the "**Firm Shares**." In addition, the Company has granted to the Underwriter an option to purchase up to an additional 750,000 Shares. The additional 750,000 Shares to be sold by the Company pursuant to such option are called the "**Optional Shares**." The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the "**Offered Shares**."

The Company has prepared and filed with the Securities and Exchange Commission (the "**Commission**") a shelf registration statement on Form S-3 (File No. 333-165677), which contains a form of prospectus (the "**Base Prospectus**") to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it was declared effective by the Commission under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Securities Act**"), including all documents incorporated or deemed to be incorporated by reference therein and any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430B under the Securities Act or the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Exchange Act**"), is called the "**Registration Statement**." Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act is called the "**Rule 462(b) Registration Statement**," and from and after the date and time of filing of the Rule 462(b) Registration Statement the term "**Registration Statement**" shall include the Rule 462(b) Registration Statement. The preliminary prospectus supplement dated July 14, 2011 describing the Offered Shares and the offering thereof, together with the Base Prospectus, is called the "**Preliminary Prospectus**." As used herein, the term "**Prospectus**" shall mean the final prospectus supplement to the Base Prospectus that describes the Offered Shares and the offering thereof, together with the Base Prospectus, in the form first used by the Underwriter to confirm sales of the Offered Shares or in the form first made available to the Underwriter by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act. As used

herein, "**Applicable Time**" is 7:00 p.m. (New York time) on July 14, 2011. As used herein, "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, and "**Time of Sale Prospectus**" means the Preliminary Prospectus, as amended or supplemented immediately prior to the Applicable Time, together with the free writing prospectuses, if any, identified in Schedule A hereto, each "road show" (as defined in Rule 433 under the Securities Act), if any, related to the offering of the Shares contemplated hereby that is a "written communication" (as defined in Rule 405 under the Securities Act), and the pricing information set forth in Schedule B hereto. As used herein, the terms "**Registration Statement**," "**Rule 462(b) Registration Statement**", "**Base Prospectus**," "**Preliminary Prospectus**," "**Time of Sale Prospectus**" and "**Prospectus**" shall include the documents incorporated and deemed to be incorporated by reference therein. All references in this Agreement to financial statements and schedules and other information which are "contained," "included" or "stated" in the Registration Statement, the Rule 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Rule 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus, as the case may be; and all references in this Agreement to amendments or supplements to the Registration Statement, the Rule 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus, as the case may be, and all references in this Agreement to amendments or supplements to the Registration Statement, the Rule 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus shall be deemed to mean and include the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in the Registration Statement, the Rule 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus, as the case may be. All references in this Agreement to (i) the Registration Statement, the 462(b) Registration Statement, the Base Prospectus, the Preliminary Prospectus or the Prospectus, or any amendments or supplements to any of the foregoing, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System ("**EDGAR**") and (ii) the Prospectus shall be deemed to include the "**electronic Prospectus**" provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(n) of this Agreement.

The Company hereby confirms its agreements with the Underwriter as follows:

Section 1. Representations and Warranties of the Company. The Company hereby represents, warrants and covenants to the Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereafter defined), if any, and covenants with the Underwriter, as follows:

(a) *Compliance with Registration Requirements*. The Registration Statement and any Rule 462(b) Registration Statement have been declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission.

The Preliminary Prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Underwriter for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became effective and at all subsequent times, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus, together with each Road Show, if any, did not, and at the time of each sale of the Offered Shares and at the First Closing Date (as defined in Section 2), the Time of Sale Prospectus, together with each Road Show, if any, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at all subsequent times, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto or any Road Show, made in reliance upon and in conformity with information relating to the Underwriter furnished to the Company in writing by the Underwriter expressly for use therein, it being understood and agreed that the only such information furnished by the Underwriter to the Company consists of the information described in Section 9(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

The Company is not an “ineligible issuer” in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement, the Preliminary Prospectus or the Prospectus, including any document incorporated by reference therein. Except for the free writing prospectuses, if any, identified in Schedule A hereto, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any free writing prospectus.

(b) *Offering Materials Furnished to Underwriter*. The Company has delivered to the Underwriter one complete manually signed copy of the Registration Statement, each amendment thereto and any Rule 462(b) Registration Statement and of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement, each amendment thereto and any Rule 462(b) Registration Statement (without exhibits) and the Base Prospectus, the Time of Sale Prospectus, the Prospectus, as amended or supplemented, and any free writing prospectus reviewed and consented to by the Underwriter, in such quantities and at such places as the Underwriter has reasonably requested.

(c) *Distribution of Offering Material By the Company*. The Company has not distributed and will not distribute, prior to the later of (i) the expiration or termination of the option granted to the Underwriter in Section 2 and (ii) the completion of the Underwriter's distribution of the Offered Shares, any offering material in connection with the offering and sale of the Offered Shares other than the Preliminary Prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus reviewed and consented to by the Underwriter, or the Registration Statement.

(d) *The Underwriting Agreement*. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(e) *Authorization of the Offered Shares*. The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares.

(f) *No Applicable Registration or Other Similar Rights*. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(g) *No Material Adverse Change*. Subsequent to the respective dates as of which information is contained in the Time of Sale Prospectus, except as disclosed or incorporated by reference in the Time of Sale Prospectus, (i) neither the Company nor the Subsidiary has not incurred any liabilities, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and the Subsidiary, or has entered into any transactions not in the ordinary course of business, (ii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or the Subsidiary, or any payment of or declaration to pay any dividends or any other distribution with respect to the Company, and (iii) there has not been any material adverse change in the properties, business, prospects, operations, earnings, assets, liabilities or condition (financial or otherwise) of the Company and the Subsidiary (each of clauses (i), (ii) and (iii), a "**Material Adverse Change**").

(h) *Independent Accountants*. Each of Ernst & Young LLP ("**Ernst & Young**") and Carlin, Charron & Rosen, LLP ("**CCR LLP**"), who have certified and expressed their opinion with respect to the financial statements including the related notes thereto and supporting schedules contained or incorporated by reference in the Registration Statement, Time of Sale Prospectus and the Prospectus, are (i) an independent registered public accounting firm with respect to the Company within the applicable rules and regulations adopted by the Commission and as required by the Securities Act, (ii) in compliance with the applicable requirements relating to the qualification of accountants under Regulation S-X and (iii) a registered public accounting firm as defined by the Public Company Accounting Oversight Board (United States) whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(i) *Preparation of the Financial Statements*. The financial statements of the Company, together with the related schedules and notes thereto, included or incorporated by reference in the Registration Statement, Time of Sale Prospectus and the Prospectus (the "**Financial Statements**"), comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly in all material respects (i) the financial condition of the Company as of the dates indicated and (ii) the consolidated results of operations, stockholders' equity and changes in cash flows of the Company for the periods therein specified; and such financial statements and related schedules and notes thereto have been prepared in conformity with United States generally accepted accounting principles, consistently applied throughout the periods involved (except as otherwise stated therein and subject, in the case of unaudited financial statements, to the absence of footnotes and normal year-end adjustments) and in accordance with the requirements of Regulation S-X. The financial data set forth under the captions "Summary Historical Financial Data" and "Selected Financial Data" included or incorporated by reference in the Registration Statement, Time of Sale Prospectus and the Prospectus has been prepared on a basis consistent with that of the Financial Statements and present fairly the financial position and results of operations of the Company as of the respective dates and for the respective periods indicated. There are no other financial statements (historical or pro forma) that would be required to be included or incorporated by reference in the Registration Statement, Time of Sale Prospectus and the Prospectus; and all disclosures contained in the Registration Statement, Time of Sale Prospectus and the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10(e) of Regulation S-K under the Securities Act, to the extent applicable, and present fairly the information shown therein and the Company's basis for using such measures. No forward-looking statement (within the meaning of Section 27A of the Act and Section 21E of the Exchange Act) contained in the Registration Statement, Time of Sale Prospectus and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed in other than good faith.

(j) *Company's Accounting System*. Each of the Company and the Subsidiary maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(k) *Incorporation and Good Standing of the Company and the Subsidiary*. Each of the Company and the Subsidiary has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware, with the corporate power and authority to own its properties and to conduct its business as currently being conducted and as described in the Time of Sale Prospectus and the Prospectus. Each of the Company and the Subsidiary is duly qualified to transact business and is in good standing as a foreign corporation in each other jurisdiction in which its ownership or leasing of property or the conduct of its business requires such qualification, except where the failure to be so qualified and in good standing or have such power or authority, individually or in the aggregate, would not result in a Material Adverse Change. The Company has no subsidiaries (as defined in Rule 405 of the Securities Act) other than Delcath Systems Limited (the "**Subsidiary**"); the Company owns all of the issued and outstanding capital stock or other equity interests of the Subsidiary; and, except as otherwise described in the Time of Sale Prospectus and the Prospectus, does not own any beneficial interest, directly or indirectly, in any other corporation, partnership, joint venture or other business entity.

(l) *Capitalization and Other Capital Stock Matters*. All of the issued and outstanding shares of capital stock of the Company and the Subsidiary have been duly authorized and validly issued, are fully paid and nonassessable and were not issued in violation of, and are not subject to, any preemptive or similar rights. The information set forth under the caption "Capitalization" in the Time of Sale Prospectus and the Prospectus (and any similar sections, if any, contained in the Time of Sale Prospectus and the Prospectus) is fairly and accurately presented on a basis consistent with the Company's Financial Statements. All of the outstanding shares of capital stock or other equity interests of the Subsidiary is owned, directly or indirectly, by the Company, free and clear of all liens, security interests, mortgages, pledges, charges, equities, claims or restrictions on transferability or encumbrances of any kind (collectively, "**Liens**"), other than those Permitted Liens and those imposed by the Securities Act and the securities or "Blue Sky" laws of certain U.S. state or non-U.S. jurisdictions. The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in the Time of Sale Prospectus and the Prospectus under the caption "Description of Capital Stock" (and any similar sections or information, if any, contained in the Time of Sale Prospectus and the Prospectus).

(m) *Stock Exchange Listing; Exchange Act Registration*. The Common Stock is registered pursuant to Section 12(b) and/or 12(g) of the Exchange Act and is listed on the NASDAQ Capital Market, and the Company has taken no action designed to, or reasonably likely to have the effect of, termination the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NASDAQ Capital Market, nor has the Company received any notification that the Commission or the NASDAQ Capital Market is contemplating terminating such registration or listing. The Company has complied in all material respects with the applicable requirements of the NASDAQ Capital Market for maintenance of inclusion of the Common Stock thereon. The Company has filed a notification of the listing of the Offered Shares on the NASDAQ Capital Market.

(n) *Non-Contravention of Existing Instruments; No Consents*. Neither the Company nor any Subsidiary is in breach or violation of or in default (nor has any event occurred which with notice, lapse of time or both would result in any breach or violation of, or constitute a default) (i) under the provisions of its charter or bylaws (or analogous governing instrument, as applicable, the "**Charter Documents**") or (ii) in the performance or observance of any term, covenant, obligation, agreement or condition contained in any indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any license, lease, contract or other agreement or instrument to which the Company or the Subsidiary is a party or by which it or any of its properties may be bound or affected (collectively, the "**Applicable Agreements**"), or (iii) in the performance or observance of any statute, law, rule, regulation, ordinance, judgment, injunction, writ, order or decree of any court, regulatory body, administrative agency,

governmental body, arbitrator or other authority having jurisdiction over the Company, the Subsidiary or any of their properties, as applicable (including, without limitation, the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act ("**FDCA**") and those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) (collectively, "**Applicable Laws**"), except, with respect to clauses (ii) and (iii) above, to the extent any such contravention has been waived or would not result in a Material Adverse Change. No approval, authorization, consent or order of or filing, qualification or registration with, any court or governmental agency or body, foreign or domestic, which has not been made, obtained or taken and is not in full force and effect, is required in connection with the execution, delivery and performance of this Agreement or the consummation of the offering of the Offered Shares by the Company other than as may be required (i) under the securities or "Blue Sky" laws of U.S. state or non-U.S. jurisdictions or other non-U.S. laws applicable to the purchase of the Securities outside the U.S. in connection with the Transactions or (ii) by the NASDAQ Capital Market in connection with an additional share listing application for the Offered Shares.

(o) *No Material Actions or Proceedings*. (i) There are no legal or governmental actions, suits, claims or proceedings pending or, to the Company's knowledge, threatened or contemplated to which the Company or the Subsidiary is or would be a party or of which any of their respective properties is or would be subject at law or in equity, before or by any federal, state, local or foreign governmental or regulatory commission, board, body, authority or agency, or before or by any self-regulatory organization or other non-governmental regulatory authority (including, without limitation, the FDA), which would be required to be described in the Time of Sale Prospectus and the Prospectus and are not so described therein, that, singularly or in the aggregate, if resolved adversely to the Company or the Subsidiary, would reasonably be likely to result in a Material Adverse Change or prevent or materially and adversely affect the ability of the Company to consummate the offering of the Offered Shares.

(p) *Intellectual Property Rights*. Each of the Company and the Subsidiary owns or possesses the right to use all patents, trademarks, trademark registrations, service marks, service mark registrations, trade names, copyrights, licenses, inventions, software, databases, know-how, Internet domain names, trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures, and other intellectual property (collectively, "**Intellectual Property**") necessary to carry on their respective businesses as currently conducted, and as proposed to be conducted and described in the Time of Sale Prospectus and the Prospectus, and neither the Company nor the Subsidiary is aware of any claim to the contrary or any challenge by any other person to the rights of the Company or the Subsidiary with respect to the foregoing except for those that could not result in a Material Adverse Change. To the Company's knowledge, the Intellectual Property is valid and enforceable, and is not infringed by any third party. All Company and Subsidiary products are properly marked with any applicable U.S. patent numbers and no Company or Subsidiary products are falsely marked with inapplicable, lapsed or expired U.S. patent numbers. The Intellectual Property licenses described in the Time of Sale Prospectus and the Prospectus are, to the Company's knowledge, valid, binding upon, and enforceable by or against the parties thereto in accordance to their terms. Each of the Company and the Subsidiary has complied in all material respects with, and is not in breach nor has received any asserted or threatened claim of breach of, any Intellectual Property license, and neither the Company nor the Subsidiary has knowledge of any breach or anticipated breach by any other person to any Intellectual Property license. The Company's and the Subsidiary's businesses as now conducted and as proposed to be conducted, to the Company's knowledge, do not and will not infringe or conflict with any patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses or other Intellectual Property or franchise right of

any person. Neither the Company nor the Subsidiary has received notice of any material claim against the Company or the Subsidiary alleging the infringement by the Company or the Subsidiary of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. Each of the Company and the Subsidiary has taken all reasonable steps to protect, maintain and safeguard its rights in all Intellectual Property, including the execution of appropriate intellectual property assignment, nondisclosure and confidentiality agreements, and no current or former employee or contractor is in violation of any such agreement or has retained any rights in such Intellectual Property. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's and the Subsidiary's right to own, use, or hold for use any of the Intellectual Property as owned, used or held for use in the conduct of the businesses as currently conducted. Neither the Company nor the Subsidiary has entered into any agreement to indemnify any third party against a claim of intellectual property infringement. Each of the Company and the Subsidiary has duly and properly filed or caused to be filed with the United States Patent and Trademark Office (the "**PTO**") and applicable foreign and international patent authorities all patent applications owned by the Company or the Subsidiary (the "**Company Patent Applications**"). To the Company's knowledge, each of the Company and the Subsidiary has complied with the PTO's duty of candor and disclosure for the Company Patent Applications and has made no material misrepresentation in the Company Patent Applications. Neither the Company nor the Subsidiary is aware of any information material to a determination of patentability regarding the Company Patent Applications not called to the attention of the PTO or similar foreign authority. Neither the Company nor the Subsidiary is aware of any information not called to the attention of the PTO or similar foreign authority that would preclude the grant of a patent for the Company Patent Applications. Neither the Company nor the Subsidiary has knowledge of any information that would preclude the Company from having clear title to the Company Patent Applications. Neither the Company nor the Subsidiary has used any open source software in any Company product. Each of the Company and the Subsidiary is in compliance with all relevant local, state, federal, and foreign laws related to the collection, storage and distribution of personally identifiable information and with all Company and Subsidiary privacy policies and all applicable agreements. The consummation of the transactions contemplated by this agreement will not violate any Company or Subsidiary privacy obligations, nor require the Company or the Subsidiary to provide any notice to, or seek any consent from, any employee, customer, supplier, service provider or other third party.

(q) *All Necessary Permits, etc*. Each of the Company and the Subsidiary has made all filings, applications and submissions required by, and owns or possesses all approvals, licenses, certificates, certifications, clearances, consents, exemptions, marks, notifications, orders, permits and other authorizations issued by, the appropriate federal, state or foreign regulatory authorities (including, without limitation, the FDA, and any other foreign, federal state or local government or regulatory authorities performing functions similar to those performed by the FDA) necessary to conduct its business as described in the Time of Sale Prospectus and the Prospectus (collectively, "**Permits**"), except for such Permits which the failure to obtain would not result in a Material Adverse Change (the "**Immaterial Permits**"), and is in compliance in all material respects with the terms and conditions of all such Permits other than the Immaterial Permits (the "**Required Permits**"). All such Required Permits held by the Company and the Subsidiary are valid and in full force and effect. Neither the Company nor the Subsidiary has received any notice of any proceedings relating to revocation or modification of, any such Required Permit, which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would result in a Material Adverse Change.

(r) *Title to Properties*. Each of the Company and the Subsidiary has good and marketable title to all property (whether real or personal) described in the Time of Sale Prospectus and the Prospectus as being owned by it, in each case free and clear of all Liens, except such as are described in the Time of Sale Prospectus and the Prospectus and those that would not, individually or in the aggregate materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiary. All of the property described in the Time of Sale Prospectus and the Prospectus as being held under lease by the Company or the Subsidiary is held thereby under leases that are in full force and effect.

(s) *Regulatory Compliance*.

(1) Neither the Company nor the Subsidiary has received any written notice or other communication from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA regarding non-compliance with the FDCA and applicable FDA regulations or similar laws, statutes, ordinances, rules, or regulations of any other foreign, federal, state or local governmental or regulatory authority, including, but not limited to, any regulatory or warning letter, untitled letter, adverse inspection finding, finding of deficiency, any other compliance or enforcement action. To the Company's knowledge, there has not been any non-compliance with or violation of any Applicable Laws by the Company or the Subsidiary that could reasonably be expected to require the issuance of any such communication, or an investigation, corrective action or enforcement action by the FDA or similar governmental or regulatory authorities. As of the date hereof, to the Company's knowledge, no review or investigation by a governmental or regulatory authorities is pending and no such review or investigation has been threatened.

(2) The clinical, pre-clinical and other studies and tests conducted by or on behalf of or sponsored by the Company or the Subsidiary or in which the Company or the Subsidiary or products or product candidates have participated that are described in the Time of Sale Prospectus and the Prospectus were and, if still pending, are being conducted in accordance in all material respects with all applicable federal, state or foreign statutes, laws, rules and regulations, as applicable (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) and in accordance in all material respects with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards. The descriptions in the Time of Sale Prospectus and the Prospectus of the results of such studies, tests and trials are accurate and complete in all material respects and fairly present the published data derived from such studies, tests and trials. Neither the Company nor the Subsidiary has received any notices or other correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA with respect to any ongoing clinical or pre-clinical studies or tests requiring the termination, suspension or material modification of such studies, tests or preclinical or clinical trials, which termination, suspension or material modification would reasonably be expected to result in a Material Adverse Effect. To the Company's knowledge, no filing or submission to the FDA or any other federal, state or foreign regulatory body, that is intended to be the basis for any approval, contains any material misstatement or omission. Each of the Company and the Subsidiary is in compliance with all applicable federal, state, local and foreign laws, regulations, orders and decrees governing their business as prescribed by the FDA, or any

other federal, state or foreign agencies or bodies, including those bodies and agencies engaged in the regulation of pharmaceuticals or biohazardous substances or materials, except where noncompliance would not, singly or in the aggregate, result in a Material Adverse Effect.

(3) Neither the Company, the Subsidiary nor, to the Company's knowledge, any of their respective directors, officers, employees or agents has been convicted of any crime or has been the subject of an FDA debarment proceeding. Neither the Company nor the Subsidiary has been nor is now subject to FDA's Applications Integrity Policy. To the Company's knowledge, neither the Company, the Subsidiary nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any applications, approvals, reports or other submissions to the FDA or any other governmental or regulatory authority, or made any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental or regulatory authority.

(4) Neither the Company, the Subsidiary nor, to the Company's knowledge, any of their respective directors, officers, employees or agents, have with respect to each of the following statutes, or regulations promulgated thereto: (i) engaged in activities under 42 U.S.C. §§ 1320a-7 or 1395nn; (ii) knowingly engaged in any activities under 42 U.S.C. § 1320a-7a or the Federal False Claims Act, 31 U.S.C. § 3729; or (iii) knowingly and willfully engaged in any activities under 42 U.S.C. § 1320a-7b, which are, as applicable, prohibited, cause for civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other State Health Care Program or Federal Health Care Program.

(t) *Tax Law Compliance*. Each of the Company and the Subsidiary (i) has timely filed all necessary federal, state, local and foreign income and franchise tax returns (or timely filed applicable extensions therefore) that have been required to be filed and (ii) is not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto, other than any which the Company or the Subsidiary is contesting in good faith and for which adequate reserves have been provided and reflected in the Company's financial statements included or incorporated by reference in the Time of Sale Prospectus and the Prospectus or except if such failure to file or pay would not, individually or in the aggregate, result in a Material Adverse Change. Neither the Company nor the Subsidiary has any tax deficiency that has been or, to the Company's knowledge, is reasonably likely to be asserted or threatened against it that would result in a Material Adverse Change.

(u) *Company Not an "Investment Company"*. The Company has been advised of the rules and requirements under the Investment Company Act of 1940, as amended (the "**Investment Company Act**"). The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Prospectus, an "**investment company**" within the meaning of Investment Company Act and will conduct its business in a manner so that it will not become subject to the Investment Company Act.

(v) *Insurance*. Each of the Company and the Subsidiary maintains or is covered by insurance provided by recognized, financially sound and reputable institutions with insurance policies in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in

similar industries. All such insurance is fully in force on the date hereof and will be fully in force as of the First Closing Date and each Option Closing Date. Neither the Company nor the Subsidiary has reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not result in a Material Adverse Change.

(w) *No Price Stabilization or Manipulation; Compliance with Regulation M*. Neither the Company nor, to the Company's knowledge, any of its officers, directors, affiliates or controlling persons has, (i) taken, directly or indirectly, any action designed to cause or to result in, or that has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company, whether to facilitate the sale or resale of any of the Offered Shares or otherwise, in each case, in a manner that violates Regulation M under the Securities Act, (ii) sold, bid for, purchased, or paid anyone any compensation for soliciting purchases of, any of the Offered Shares, or (iii) except as disclosed in the Time of Sale Prospectus and the Prospectus, paid or agreed to pay to any person any compensation for soliciting another to purchase any other securities of the Company.

(x) *No Undisclosed Relationships*. No relationship, direct or indirect, exists between or among the Company on the one hand and the directors, officers, stockholders, customers or suppliers of the Company or any of their affiliates on the other hand, which would be required to be described in the Registration Statement, Time of Sale Prospectus and the Prospectus or a document incorporated by reference therein, which has not been so described.

(y) *FINRA Matters*. The Company satisfies the eligibility requirements in existence immediately prior to October 21, 1992 for the use of a registration statement on Form S-3 for the offering of the Offered Shares.

(z) *Parties to Lock-Up Agreements*. Each of the Company's directors and executive officers listed in Schedule C has executed and delivered to the Underwriter a lock-up agreement in the form of Exhibit A hereto. Schedule C hereto contains a true, complete and correct list of all directors and executive officers of the Company.

(aa) *Statistical and Market-Related Data*. Any statistical, industry-related and market-related data included or incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus, are based on or derived from sources that the Company reasonably and in good faith believes to be reliable and accurate, and such data agree with the sources from which they are derived.

(bb) *No Unlawful Contributions or Other Payments*. Neither the Company nor the Subsidiary nor, to the best of the Company's knowledge, any employee or agent of the Company or the Subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(cc) *Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting*. The Company and the Subsidiary have established, maintain and evaluate "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act), which (i) are designed to ensure that material information relating to the Company is made known to the Company's and the Subsidiary's principal executive officer and its principal financial officer by others within those entities, (ii) have been evaluated for effectiveness as of the end of the last fiscal period covered by the Time of Sale

Prospectus and the Prospectus, and (iii) such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established. There are no significant deficiencies and material weaknesses in the design or operation of internal controls which could adversely affect the Company's or the Subsidiary's ability to record, process, summarize, and report financial data to management and the Board of Directors of the Company. The Company is not aware of any fraud, whether or not material, that involves management or other employees who have a role in the Company's or the Subsidiary's internal controls; and since the date of the most recent evaluation of such disclosure controls and procedures, there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

(dd) *Compliance with Environmental Laws*. Each of the Company and the Subsidiary (i) is in compliance with any and all applicable foreign, federal, state and local laws, orders, rules, regulations, directives, decrees and judgments relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of human health and safety or the environment which are applicable to their businesses ("**Environmental Laws**"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business; and (iii) is in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, individually or in the aggregate, result in a Material Adverse Change. There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, individually or in the aggregate, result in a Material Adverse Change.

(ee) *ERISA Compliance*. Neither the Company, nor the Subsidiary nor any other entity that together with the Company and the Subsidiary would be considered a single employer within the meaning of Section 4001(b) of ERISA (an "**ERISA Affiliate**") maintains or contributes to or ever maintained was required to contribute to a plan subject to Title IV of ERISA or Section 412 of the Internal Revenue Code of 1986, as amended (the "**Code**"). Each benefit plan sponsored by the Company or an ERISA Affiliate has been maintained in substantial compliance with its terms and applicable laws. Each such plan intended to be "qualified" within the meaning of Section 401(a) of the Code is the subject of a favorable determination letter from the Internal Revenue Service as to its qualification (or the period for timely requesting such a determination has not expired) and the Company and the Subsidiary are aware of no circumstances that would reasonably be expected to result in the disqualification of such plan.

(ff) *Brokers*. There are no contracts, agreements or understandings between the Company and any person (other than this Agreement) that would give rise to a valid claim against the Company or the Underwriter for a brokerage commission, finder's fee or other like payment in connection with the offering and sale of the Offered Shares.

(gg) *No Outstanding Loans or Other Extensions of Credit*. Since the adoption of Section 13(k) of the Exchange Act, neither the Company nor the Subsidiary has extended or maintained credit, arranged for the extension of credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company
and/or such Subsidiary except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

(hh) *Compliance with Laws.* The Company has not been advised, and has no reason to believe, that it and the Subsidiary are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Change.

(ii) *No Conflicts*. Neither the execution, delivery or performance of this Agreement nor the consummation of any of the transactions contemplated herein will (i) conflict with or result in a breach or violation of, or constitute a default under (nor constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under), give rise to any right of termination or other right or the cancellation or acceleration of any right or obligation or loss of a benefit under, or give rise to the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company or the Subsidiary pursuant to any Applicable Agreement, (ii) result in any violation of the provisions of the charter or by-laws of the Company or the Subsidiary, or (iii) result in any violation of any Applicable Law.

(jj) *Sarbanes-Oxley Act*. The Company, the Subsidiary, and to its knowledge, all of the Company's and the Subsidiary's directors or officers, in their capacities as such, is in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act and any related rules and regulations promulgated by the Commission. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it with the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(kk) *Corporate Records*. The minute books of the Company and the Subsidiary, representing all existing records of all meetings and actions of the board of directors (including, Audit, Compensation and Stock Option, and Nominating Committees) and stockholders of the Company and the Subsidiary (collectively, the "**Corporate Records**") through the date of the latest meeting and action have been made available to the Underwriter and counsel for the Underwriter. All such Corporate Records are complete and accurately reflect, in all material respects, all transactions referred to in such Corporate Records. There are no material transactions, agreements or other actions that have been consummated by the Company or the Subsidiary that are not properly approved and/or recorded in the Corporate Records of the Company and the Subsidiary.

(ll) *Dividend Restrictions*. Except as otherwise disclosed in the Time of Sale Prospectus and the Prospectus, there will be no encumbrances or restrictions on the ability of the Subsidiary (x) to pay dividends or make other distributions on such Subsidiary's capital stock or to pay any indebtedness to the Company, (y) to make loans or advances or pay any indebtedness to, or investments in, the Company or (z) to transfer any of its property or assets to the Company.

(mm) *No Labor Disputes*. No labor problem or dispute with the employees of the Company or the Subsidiary exists, or, to the Company's knowledge, is threatened or imminent, which would reasonably be expected to result in a Material Adverse Change. Neither the

Company nor the Subsidiary is aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company. Neither the Company nor the Subsidiary has engaged in any unfair labor practice; except for matters which would not, individually or in the aggregate, result in a Material Adverse Change, (i) there is (A) no unfair labor practice complaint pending or, to the Company's knowledge, threatened against the Company or the Subsidiary before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under collective bargaining agreements is pending or to the Company's knowledge, threatened, (B) no strike, labor dispute, slowdown or stoppage pending or, to the Company's knowledge, threatened against the Company or the Subsidiary and (C) no union representation dispute currently existing concerning the employees of the Company and (ii) to the Company's knowledge, (A) no union organizing activities are currently taking place concerning the employees of the Company or the Subsidiary and (B) there has been no violation of any federal, state, local or foreign law relating to discrimination in the hiring, promotion or pay of employees, any applicable wage or hour laws or any provision of the Employee Retirement Income Security Act of 1974 ("**ERISA**") or the rules and regulations promulgated thereunder concerning the employees of the Company or the Subsidiary .

(nn) *Foreign Corrupt Practices Act*. Neither the Company, the Subsidiary nor, to the Company's knowledge, any other person associated with or acting on behalf of the Company or the Subsidiary, including without limitation any director, officer, agent or employee of the Company or the Subsidiary has, directly or indirectly, while acting on behalf of the Company or the Subsidiary (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity or failed to disclose fully any contribution in violation of law, (ii) made any payment to any federal or state governmental officer or official, o other person charged with similar public or quasi-public duties, other than payments required or permitted by the laws of the United States or any jurisdiction thereof, (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.

(oo) *Money Laundering Laws*. The operations of the Company and the Subsidiary are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or the Subsidiary with respect to the Money Laundering Laws is pending, or to the Company's knowledge, threatened against the Company or the Subsidiary.

(pp) *OFAC*. Neither the Company, the Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or the Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and neither the Company nor the Subsidiary will directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any affiliate, joint venture partner or other person or entity, which, to the Company's knowledge, will use such proceeds for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

Any certificate signed by any officer of the Company and delivered to the Underwriter or to counsel for the Underwriter shall be deemed a representation and warranty by the Company to the Underwriter as to the matters covered thereby.

The Company acknowledges that the Underwriter and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriter, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 2. Purchase, Sale and Delivery of the Offered Shares.

(a) *The Firm Shares*. Upon the terms herein set forth, the Company agrees to issue and sell to the Underwriter, and on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriter agrees to purchase from the Company, an aggregate of 5,000,000 Firm Shares. The purchase price per Firm Share to be paid by the Underwriter to the Company shall be $4.75 per share.

(b) *The First Closing Date*. Delivery of certificates for the Firm Shares to be purchased by the Underwriter and payment therefor shall be made at the offices of Jefferies, 520 Madison Avenue, New York, New York (or such other place as may be agreed to by the Company and the Underwriter) at 9:00 a.m. New York time, on July 20, 2011, or such other time and date as the Underwriter shall designate by notice to the Company (the time and date of such closing are called the "**First Closing Date**"). The Company hereby acknowledges that circumstances under which Jefferies may provide notice to postpone the First Closing Date as originally scheduled include, but are in no way limited to, any determination by the Company or the Underwriter to recirculate to the public copies of an amended or supplemented Prospectus.

(c) *The Optional Shares; Option Closing Date*. In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the Underwriter to purchase up to an aggregate of 750,000 Optional Shares from the Company at the purchase price per share to be paid by the Underwriter for the Firm Shares. The option granted hereunder is for use by the Underwriter solely in covering any over-allotments in connection with the sale and distribution of the Firm Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Underwriter to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriter is exercising the option, (ii) the names and denominations in which the certificates for the Optional Shares are to be registered and (iii) the time, date and place at which such certificates will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term "**First Closing Date**" shall refer to the time and date of delivery of certificates for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an "**Option Closing Date**" and shall be determined by the Underwriter and shall not be earlier than three nor later than five full business days after delivery of such notice of exercise. The Underwriter may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

(d) *Public Offering of the Offered Shares*. The Underwriter hereby advises the Company that the Underwriter intends to offer for sale to the public, initially on the terms set forth in the Time of Sale Prospectus and the Prospectus, the Offered Shares as soon after this Agreement has been executed as the Underwriter, in its sole judgment, has determined is advisable and practicable.

(e) *Payment for the Offered Shares*. Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(f) *Delivery of the Offered Shares*. The Company shall deliver, or cause to be delivered, to the Underwriter certificates for the Firm Shares at the First Closing Date, against the irrevocable release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered, to the Underwriter certificates for the Optional Shares the Underwriter has agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the irrevocable release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The certificates for the Offered Shares shall be in definitive form and registered in such names and denominations as the Underwriter shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be) and shall be made available for inspection on the business day preceding the First Closing Date (or the applicable Option Closing Date, as the case may be) at a location in New York City as the Underwriter may designate. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriter.

Section 3. Additional Covenants of the Company. The Company further covenants and agrees with the Underwriter as follows:

(a) *Delivery of Registration Statement, Time of Sale Prospectus and Prospectus*. The Company shall furnish to you, without charge, two signed copies of the Registration Statement, any amendments thereto and any Rule 462(b) Registration Statement (including exhibits thereto) and shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period mentioned in Section 3(e) or 3(f) below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) *Underwriter's Review of Proposed Amendments and Supplements*. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act), the Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus (including any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Underwriter for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Underwriter's consent, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) *Free Writing Prospectuses*. The Company shall furnish to the Underwriter for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without

the Underwriter's consent. The Company shall furnish to the Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Underwriter for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Underwriter's consent.

(d) *Filing of Underwriter Free Writing Prospectuses*. The Company shall not to take any action that would result in the Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

(e) *Amendments and Supplements to Time of Sale Prospectus*. If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriter, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, including the Securities Act, the Company shall (subject to Sections 3(a) and 3(b)) forthwith prepare, file with the Commission and furnish, at its own expense, to the Underwriter and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act.

(f) *Securities Act Compliance*. After the date of this Agreement, the Company shall promptly advise the Underwriter in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (ii) of the time and date of any

filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to any Preliminary Prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to any Preliminary Prospectus, the Time of Sale Prospectus or the Prospectus or of any order preventing or suspending the use of any Preliminary Prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) *Amendments and Supplements to the Prospectus and Other Securities Act Matters*. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Underwriter or counsel for the Underwriter it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 3(a) and 3(b)) to promptly prepare, file with the Commission and furnish at its own expense to the Underwriter and to dealers, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Underwriter's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Sections 3(a) or (b).

(h) *Blue Sky Compliance*. The Company shall cooperate with the Underwriter and counsel for the Underwriter to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Underwriter, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Underwriter promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

(i) *Use of Proceeds*. The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in the manner described under the caption "Use of Proceeds" in the Prospectus.

(j) *Transfer Agent*. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) *Earnings Statement*. As soon as practicable, but in any event no later than sixteen months after the date of this Agreement, the Company will make generally available to its security holders and to the Underwriter an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(l) *Exchange Act Compliance*. The Company shall file all documents required to be filed with the Commission pursuant to Sections 13(a), 13(d), 13(e), 13(g), 14 or 15(d) of the Exchange Act in the manner and within the time periods required by the Exchange Act.

(m) *Listing*. The Company will use its best efforts to list, subject to notice of issuance, the Offered Shares on the NASDAQ Capital Market and to maintain the listing of the Shares on the NASDAQ Capital Market.

(n) *Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet*. The Company shall cause to be prepared and delivered, at its expense, within one business day from the effective date of this Agreement, to Jefferies an "**electronic Prospectus**" to be used by the Underwriter in connection with the offering and sale of the Offered Shares. As used herein, the term "**electronic Prospectus**" means a form of Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to Jefferies, that may be transmitted electronically by Jefferies to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the Prospectus printed on paper, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to Jefferies, that will allow investors to store and have continuously ready access to the Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Prospectus.

(o) *Agreement Not to Offer or Sell Additional Shares*. During the period commencing on and including the date hereof and ending on and including the 90th day following the date of the Prospectus (as the same may be extended as described below, the "**Lock-up Period**"), the Company will not, without the prior written consent of Jefferies (which consent may be withheld at the sole discretion of Jefferies), directly or indirectly, sell (including, without limitation, any short sale), offer, contract or grant any option to sell, pledge, assign, transfer or establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or otherwise dispose of or transfer, or announce the offering of, or file any registration statement under the Securities Act in respect of, any Shares, options, rights or warrants to acquire Shares or

securities exchangeable or exercisable for or convertible into Shares (other than as contemplated by this Agreement with respect to the Offered Shares) or publicly announce the intention to do any of the foregoing; provided, however, that the Company may issue Shares or options to purchase Shares, or issue Shares upon exercise of options, pursuant to any employee benefit, stock option, stock bonus or other stock plan or arrangement described in the Prospectus. Notwithstanding the foregoing, if (i) during the last 17 days of the Lock-up Period, the Company issues an earnings release or material news or a material event relating to the Company occurs, (ii) enter into any swap, hedge or similar arrangement or agreement that transfers in whole or in part, the economic risk of ownership of the Shares, or securities exchangeable or exercisable for or convertible into Shares currently or hereafter owned either of record or beneficially by the Company or (iii) prior to the expiration of the Lock-up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Lock-up Period, then in each case the Lock-up Period will be extended until the expiration of the 18-day period beginning on the date of the issuance of the earnings release or the occurrence of the material news or material event, as applicable, unless Jefferies waives, in writing, such extension (which waiver may be withheld at the sole discretion of Jefferies), except that such extension will not apply if, (i) within three business days prior to the 15th calendar day before the last day of the Lock-up Period, the Company delivers a certificate, signed by the Chief Financial Officer or Chief Executive Officer of the Company, certifying on behalf of the Company that (i) the Shares are "actively traded securities" (as defined in Regulation M), (ii) the Company meets the applicable requirements of paragraph (a)(1) of Rule 139 under the Securities Act in the manner contemplated by NASD Conduct Rule 2711(f)(4), and (iii) the provisions of NASD Conduct Rule 2711(f)(4) are not applicable to any research reports relating to the Company published or distributed by the Underwriter during the 15 days before or after the last day of the Lock-up Period (before giving effect to such extension). The Company will provide the Underwriter with prior notice of any such announcement that gives rise to an extension of the Lock-up Period.

(p) *Future Reports to the Underwriter*. During the period of five years hereafter the Company will furnish or make available to Jefferies at 520 Madison Avenue, New York, New York Attention: Capital Markets: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders' equity and cash flows for the year then ended and the opinion thereon of the Company's independent public or certified public accountants; (ii) as soon as practicable after the filing thereof, copies of each proxy statement, Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report filed by the Company with the Commission, FINRA or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; provided however, that all requirements of this subsection (p) shall be satisfied to the extent the reports, communications, financial statements or other documents referenced herein are available on EDGAR.

(q) *Investment Limitation*. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company or its Subsidiary to register as an investment company under the Investment Company Act.

(r) *No Stabilization or Manipulation; Compliance with Regulation M*. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of

Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Offered Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Underwriter (or, if later, at the time stated in the notice), the Company will, and shall cause each of its affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply.

(s) *Lock-Up Agreements*. During the Lock-up Period, the Company will enforce all existing agreements between the Company and any of its security holders that prohibit the sale, transfer, assignment, pledge or hypothecation of any of the Company's securities. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such existing "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors pursuant to Section 6(j).

Section 4. Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriter, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each Preliminary Prospectus, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Underwriter in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Underwriter, preparing and printing a "**Blue Sky Survey**" or memorandum and a "Canadian wrapper", and any supplements thereto, advising the Underwriter of such qualifications, registrations, determinations and exemptions, (vii) the filing fees incident to, and the reasonable fees and expenses of counsel for the Underwriter in connection with, the FINRA's review, if any, and approval of the Underwriter's participation in the offering and distribution of the Offered Shares, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Underwriter and any such consultants, and the cost of any aircraft chartered in connection with the road show, (ix) the fees and expenses associated with listing the Offered Shares on the NASDAQ Capital Market, and (ix) all other fees, costs and expenses of the nature referred to in Item 14 of Part II of the Registration Statement. Except as provided in this Section 4, Section 7, Section 9 and Section 10 hereof, the Underwriter shall pay its own expenses, including the fees and disbursements of its counsel.

Section 5. Covenant of the Underwriter. The Underwriter covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

Section 6. Conditions of the Obligations of the Underwriter. The obligations of the Underwriter to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) *Accountants' Comfort Letter*. On the date hereof, the Underwriter shall have received from each of Ernst & Young and CCR LLP, each independent public or certified public accountants for the Company, (i) a letter dated the date hereof addressed to the Underwriter, in form and substance satisfactory to the Underwriter, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Preliminary Prospectus, Time of Sale Prospectus, and each free writing prospectus, if any, and, with respect to each letter dated the date hereof only, the Prospectus, and (ii) confirming that they are (A) independent public or certified public accountants as required by the Securities Act and the Exchange Act and (B) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X.

(b) *Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.* For the period from and after effectiveness of this Agreement and prior to the First Closing Date and, with respect to the Optional Shares, each Option Closing Date:

(i) the Company shall have filed the Prospectus with the Commission (including the information previously omitted from the Registration Statement pursuant to Rule 430B under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information previously omitted pursuant to such Rule 430B, and such post-effective amendment shall have become effective;

(ii) no stop order suspending the effectiveness of the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment to the Registration Statement, shall be in effect and no proceedings for such purpose shall have been instituted or threatened by the Commission; and

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(c) *No Material Adverse Change*. For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to the Optional Shares, each Option Closing Date in the judgment of the Underwriter there shall not have occurred any Material Adverse Change.

(d) *Opinion of Counsel for the Company*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received the opinion of Skadden, Arps, Slate, Meagher & Flom LLP, counsel for the Company, dated as of such Closing Date, the form of which is attached as Exhibit B and to such further effect as counsel for the Underwriter shall reasonably request.

(e) *Opinion of Intellectual Property Counsel for the Company*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received the opinion of Greenberg Traurig, LLP, intellectual property counsel for the Company, dated as of such Closing Date, the form of which is attached as Exhibit C and to such further effect as counsel for the Underwriter shall reasonably request.

(f) *Opinion of Regulatory Counsel for the Company*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received the opinion of Latham & Watkins LLP, regulatory counsel for the Company, dated as of such Closing Date, the form of which is attached as Exhibit D and to such further effect as counsel for the Underwriter shall reasonably request.

(g) *Opinion of Counsel for the Underwriter*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received the opinion of Goodwin Procter LLP, counsel for the Underwriter, in form and substance satisfactory to the Underwriter, dated as of such Closing Date.

(h) *Officers' Certificate*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received a written certificate executed by the Chief Executive Officer or President of the Company and the Chief Financial Officer of the Company, dated as of such Closing Date, to the effect set forth in subsections (b)(ii) of this Section 6, and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such Closing Date, there has not occurred any Material Adverse Change;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such Closing Date; and

(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such Closing Date.

(i) *Bring-down Comfort Letter*. On each of the First Closing Date and each Option Closing Date the Underwriter shall have received from each of Ernst & Young and CCR LLP, each independent public or certified public accountants for the Company, a letter dated such date, in form and substance satisfactory to the Underwriter, to the effect that they reaffirm the statements made in the letter furnished by them pursuant to subsection (a) of this Section 6, except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be.

(j) *Lock-Up Agreements*. On or prior to the date hereof, the Company shall have furnished to the Underwriter an agreement in the form of Exhibit A hereto from the persons listed on Schedule C hereto, and such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(k) *Nasdaq*. The Offered Shares shall have been approved for listing on the NASDAQ Capital Market, subject only to official notice of issuance.

(l) *Additional Documents*. On or before each of the First Closing Date and each Option Closing Date, the Underwriter and counsel for the Underwriter shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be reasonably satisfactory in form and substance to the Underwriter and counsel for the Underwriter.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Underwriter by notice to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

Section 7. Reimbursement of Underwriter's Expenses. If this Agreement is terminated by the Underwriter pursuant to Section 6 as a result of the failure of any of the conditions of Section 6 to be satisfied when and as required to be satisfied, or if the sale to the Underwriter of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Underwriter upon demand for all out-of-pocket expenses that shall have been reasonably incurred by the Underwriter in connection with the proposed purchase and the offering and sale of the Offered Shares, including but not limited to fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges.

Section 8. Effectiveness of this Agreement. This Agreement shall become effective upon the execution of this Agreement by the parties hereto.

Section 9. Indemnification.

(a) *Indemnification of the Underwriter*. The Company agrees to indemnify and hold harmless the Underwriter, its officers and employees, and each person, if any, who controls the Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Underwriter or such officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the

Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, the Time of Sale Prospectus, any free writing prospectus, any Road Show, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; or (iii) any act or failure to act or any alleged act or failure to act by the Underwriter in connection with, or relating in any manner to, the Shares or the offering contemplated hereby, and which is included as part of or referred to in any loss, claim, damage, liability or action arising out of or based upon any matter covered by clause (i) or (ii) above; and to reimburse the Underwriter and each such officer, employee, agent and controlling person for any and all expenses (including the fees and disbursements of counsel chosen by Jefferies) as such expenses are reasonably incurred by such Underwriter or such officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Underwriter expressly for use in the Registration Statement, any Preliminary Prospectus, the Time of Sale Prospectus, any Road Show, any such free writing prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Underwriter to the Company consists of the information described in subsection (b) below. The indemnity agreement set forth in this Section 9(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) *Indemnification of the Company, its Directors and Officers*. The Underwriter agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, any Preliminary Prospectus the Time of Sale Prospectus, any Road Show, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or such amendment or supplement thereto), or arises out of or is based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such Preliminary Prospectus, the Time of Sale Prospectus, such Road Show, such free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, the Prospectus (or such amendment or supplement thereto), in reliance upon and in conformity with written information furnished to the Company by the Underwriter expressly for use therein; and to reimburse the Company, or any

such director, officer or controlling person for any legal and other expense reasonably incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the Underwriter has furnished to the Company expressly for use in the Registration Statement, any Preliminary Prospectus, the Time of Sale Prospectus, any Road Show, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto) are the statements set forth in the third sentence of the third paragraph and the fourth, thirteenth, fourteenth, fifteenth and sixteenth paragraphs under the caption "Underwriting" in the Prospectus. The indemnity agreement set forth in this Section 9(b) shall be in addition to any liabilities that the Underwriter may otherwise have.

(c) *Notifications and Other Indemnification Procedures*. Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 9 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by Jefferies (in the case of counsel for the indemnified parties referred to in Section 9(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 9(b) above)) (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) *Settlements*. The indemnifying party under this Section 9 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 9(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

Section 10. Contribution. If the indemnification provided for in Section 9 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, from the offering of the Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriter, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriter, in each case as set forth on the front cover page of the Prospectus bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriter, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriter, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 9(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 9(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 10; *provided, however,* that no additional notice shall be required with respect to any action for which notice has been given under Section 9(c) for purposes of indemnification.

The Company and the Underwriter agree that it would not be just and equitable if contribution pursuant to this Section 10 were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 10.

Notwithstanding the provisions of this Section 10, the Underwriter shall not be required to contribute any amount in excess of the underwriting discounts and commissions received by the Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 10, each officer, employee and agent of the Underwriter and each person, if any, who controls the Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company with the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 11. [Reserved.]

Section 12. Termination of this Agreement. Prior to the purchase of the Firm Shares by the Underwriter on the First Closing Date this Agreement may be terminated by the Underwriter by notice given to the Company if at any time (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the NASDAQ Capital Market, or trading in securities generally on either the Nasdaq Stock Market or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal, New York or Delaware authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Underwriter is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Underwriter may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to the Underwriter, except that the Company shall be obligated to reimburse the expenses of the Underwriter pursuant to Sections 4 and 7 hereof, (b) the Underwriter to the Company, or (c) of any party hereto to any other party except that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related

discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriter, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction the Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) the Underwriter has not assumed or will not assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether the Underwriter has advised or is currently advising the Company on other matters) and the Underwriter has no obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriter and its affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriter has not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

Section 13. Representations and Indemnities to Survive Delivery. The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Underwriter set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

Section 14. Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Underwriter:

Jefferies & Company, Inc.
520 Madison Avenue
New York, New York 10022
Facsimile: (212) 284-2280
Attention: General Counsel

If to the Company:

Delcath Systems, Inc.
810 Seventh Avenue
Suite 3505
New York, New York 10019
Facsimile: (212) 489-2102
Attention: General Counsel

Any party hereto may change the address for receipt of communications by giving written notice to the others.

Section 15. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and to the benefit of the employees, agents, officers and directors and controlling persons referred to in Section 9 and Section 10, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Offered Shares as such from the Underwriter merely by reason of such purchase.

Section 16. Partial Unenforceability. The invalidity or unenforceability of any Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

Section 17. Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "**Related Judgment**"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

With respect to any Related Proceeding, each party irrevocably waives, to the fullest extent permitted by applicable law, all immunity (whether on the basis of sovereignty or otherwise) from jurisdiction, service of process, attachment (both before and after judgment) and execution to which it might otherwise be entitled in the Specified Courts, and with respect to any Related Judgment, each party waives any such immunity in the Specified Courts or any other court of competent jurisdiction, and will not raise or claim or cause to be pleaded any such immunity at or in respect of any such Related Proceeding or Related Judgment, including, without limitation, any immunity pursuant to the United States Foreign Sovereign Immunities Act of 1976, as amended.

Section 18. General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Table of Contents and the Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution

provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Sections 9 and 10 hereto fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any Preliminary Prospectus, the Time of Sale Prospectus, each Road Show, each free writing prospectus and the Prospectus (and any amendments and supplements thereto), as required by the Securities Act and the Exchange Act.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

DELCATH SYSTEMS, INC.

By: /s/ Eamonn P. Hobbs
Name: Eamonn P. Hobbs
Title: President and Chief Executive Officer

The foregoing Underwriting Agreement is hereby confirmed and accepted by the Underwriter in New York, New York as of the date first above written.

JEFFERIES & COMPANY, INC.

By: /s/ Kevin J. Sheridan
Name: Kevin J. Sheridan
Title: Managing Director

SCHEDULE A

Schedule of Free Writing Prospectuses included in the Time of Sale Prospectus

None.

SCHEDULE B

Schedule of Pricing Information Included in the Time of Sale Prospectus

Price per share to the public: $5.05

Number of shares being sold: 5,000,000

Number of shares potentially issuable pursuant to the overallotment option: 750,000

SCHEDULE C

List of Persons Executing Lock-Up Agreements

Eamonn P. Hobbs
Douglas G. Watson
Gabriel Leung
Laura A. Philips
Roger G. Stoll
Harold S. Koplewicz
Robert B. Ladd
David A. McDonald
Agustin V. Gago
Peter J. Graham
Krishna Kandarpa, M.D., Ph.D.
John Purpura
Barbra Keck
Harold C. Mapes Jr.

EXHIBIT A

Form of Lock-up Agreement

July , 2011

Jefferies & Company, Inc.
520 Madison Avenue
New York, New York 10022

RE: Delcath Systems, Inc. (the "**Company**")

Ladies and Gentlemen:

The undersigned, a shareholder and an officer and/or director of the Company, understands that Jefferies & Company, Inc. (the "**Underwriter**"), proposes to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with the Company providing for the public offering (the "**Offering**"), under the Securities Act of 1933, as amended (the "**Securities Act**") of shares of the Company's common stock (the "**Common Stock**"), par value $0.01 per share (the "**Initial Shares**"), and the grant by the Company to the Underwriter of the option to purchase additional shares of Common Stock (the "**Option Shares**"). The Initial Shares, together with the Option Shares, are collectively referred to as the "**Shares**." Capitalized terms used but not defined herein have the meanings given to them in the Underwriting Agreement. The undersigned acknowledges that you are relying on the representations and agreements of the undersigned contained in this letter agreement in carrying out the Offering and, at a subsequent date, entering into any purchase arrangements with the Company with respect to the Offering.

In consideration of the foregoing, the undersigned hereby agrees that the undersigned will not, (and will cause any spouse or immediate family member of the spouse or the undersigned living in the undersigned's household not to), without the prior written consent of Jefferies & Company, Inc. (which consent may be withheld in its sole discretion), directly or indirectly, sell, offer, contract or grant any option to sell (including without limitation any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of Common Stock or any such other securities, or otherwise dispose of any shares of Common Stock (including, without limitation, Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act, as the same may be amended or supplemented from time to time (such shares, the "**Beneficially Owned Shares**"), options or warrants to acquire shares of Common Stock or Beneficially Owned Shares, or securities exchangeable or exercisable for or convertible into shares of Common Stock or Beneficially Owned Shares currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned (or such spouse or family member), or publicly announce an intention to do any of the foregoing, for a period commencing on the date hereof and continuing through the close of trading on the date 90 days after the date of the Prospectus (the "**Lock-up Period**"); provided, that if (i) during the last 17 days of the Lock-up Period, the Company issues an earnings release or material news or a material event relating to the Company occurs or (ii) prior to the expiration of the Lock-up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Lock-up Period, then in each case the Lock-up Period will be extended until the expiration of the 18-day period beginning on the date of the issuance of the earnings release or the occurrence of the material news or material event, as

applicable, unless Jefferies & Company, Inc. waives, in writing, such extension, except that such extension will not apply if, (i) within three business days prior to the 15th calendar day before the last day of the Lock-up Period, the Company delivers a certificate, signed by the Chief Financial Officer or Chief Executive Officer of the Company, certifying on behalf of the Company that (i) the shares of Common Stock are "actively traded securities" (as defined in Regulation M), (ii) the Company meets the applicable requirements of paragraph (a)(1) of Rule 139 under the Securities Act in the manner contemplated by NASD Conduct Rule 2711(f)(4), and (iii) the provisions of NASD Conduct Rule 2711(f)(4) are not applicable to any research reports relating to the Company published or distributed by the Underwriter during the 15 days before or after the last day of the Lock-up Period (before giving effect to such extension); provided, further, that the foregoing restrictions shall not apply to:

(1) if the undersigned is a natural person, (i) any transfers made by the undersigned (a) as a bona fide gift to any member of the immediate family of the undersigned or to a trust, family partnership or family company the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family, (b) by will or intestate succession upon the death of the undersigned, or (c) as a bona fide gift, (ii) the purchase or sale of the Company's securities pursuant to a plan, contract or instruction that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act, or (iii) the disposition of shares of Common Stock to satisfy any tax withholding obligations upon the vesting of stock options held by the undersigned,

(2) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfers to any shareholder, partner or member of, or owner of a similar equity interest in, the undersigned, as the case may be, if, in any such case, such transfer is not for value, and

(3) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfer made by the undersigned (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this letter agreement or (b) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate (as defined below) of the undersigned and such transfer is not for value;

provided, *however*, that in any such case, it shall be a condition to such transfer that (A) the transferee executes and delivers to Jefferies & Company, Inc. an agreement stating that the transferee is receiving and holding the shares of Common Stock subject to the provisions of this letter agreement, and there shall be no further transfer of such shares of Common Stock, except in accordance with this letter agreement and (B) no public disclosure and no filing by any party to the transfer (donor, donee, transferor or transferee) under the Exchange Act shall be required nor shall be voluntarily made reporting a reduction in beneficial ownership of the shares of Common Stock in connection with such transfer or distribution prior to the expiration of the Lock-up Period (as the same may be extended pursuant to the terms hereof).

In addition, the undersigned may at any time after the date hereof enter into a trading plan or modify an existing trading plan that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act if then permitted by the Company and applicable law.

The undersigned hereby acknowledges and agrees that written notice of any extension of the Lock-up Period pursuant to the preceding paragraph will be delivered by Jefferies & Company, Inc. to the Company and that any such notice properly delivered will be deemed to have been given to, and received by, the undersigned.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of shares of Common Stock or securities convertible into or exchangeable or exercisable for shares of Common Stock held by the undersigned except in compliance with the foregoing restrictions.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of any shares of Common Stock owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering, if applicable.

This letter agreement is irrevocable and will be binding on the undersigned and the respective successors, heirs, personal representatives, and assigns of the undersigned.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this letter agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

Printed Name of Holder

By: _____
Signature

_____
Printed Name of Person Signing

(and indicate capacity of person signing if signing as custodian, trustee, or on behalf of an entity)

EXHIBIT B

Form of Opinion of Company Counsel

July , 2011

Jefferies & Company, Inc.
520 Madison Avenue, 6th Floor
New York, NY 10022

Re: Delcath Systems, Inc. – Offering of Common Stock

Ladies and Gentlemen:

We have acted as special counsel to Delcath Systems, Inc., a Delaware corporation (the "Company"), in connection with the Underwriting Agreement, dated July 14, 2011 (the "Underwriting Agreement"), between you and the Company, relating to the sale by the Company to you of 5,000,000 shares (the "Firm Shares") of the Company's Common Stock, par value $0.01 per share ("Common Stock"), and up to an additional 750,000 shares of Common Stock (the "Option Shares") at your option to cover over-allotments. The Firm Shares and the Option Shares are collectively referred to herein as the "Securities."

This opinion is being furnished to you pursuant to Section 6(d) of the Underwriting Agreement.

In rendering the opinions stated herein, we have examined and relied upon the following:

(a) the registration statement on Form S-3 (File No. 333-165677) of the Company relating to the Securities and other securities of the Company filed on March 24, 2010 with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933 (the "Securities Act") allowing for delayed offerings pursuant to Rule 415 of the General Rules and Regulations under the Securities Act (the "Rules and Regulations"), including information deemed to be a part of the registration statement pursuant to Rule 430B of the Rules and Regulations and the Notice of Effectiveness of the Commission posted on its website declaring such registration statement effective as of April 13, 2010 (such registration statement, at the time it became effective, being hereinafter referred to as the "Registration Statement");

(b) the prospectus, dated April 13, 2010 (the "Base Prospectus"), which forms a part of and is included in the Registration Statement;

(c) the preliminary prospectus supplement, dated July 14, 2011 (the "Preliminary Prospectus Supplement" and, together with the Base Prospectus and the Incorporated Documents (as defined below), the "Preliminary Prospectus"), relating to the offering of the Securities in the form filed by the Company with the Commission pursuant to Rule 424(b) of the Rules and Regulations;

(d) the final prospectus supplement, dated July 14, 2011 (the "Prospectus Supplement" and, together with the Base Prospectus and the Incorporated Documents, the "Prospectus"), relating to the offering of the Securities in the form filed by the Company with the Commission pursuant to Rule 424(b) of the Rules and Regulations;

(e) the documents described on Schedule I hereto filed by the Company with the Commission pursuant to the Securities Exchange Act of 1934 and incorporated by reference into the Preliminary Prospectus or the Prospectus, s the case may be, as of the date of the Preliminary Prospectus Supplement or Prospectus Supplement, respectively (the "Incorporated Documents");

(f) an executed copy of the Underwriting Agreement;

(g) a copy of the Amended and Restated Certificate of Incorporation of the Company, certified by the Secretary of State of the State of Delaware as of July 20, 2011, and certified pursuant to the Secretary's Certificate (as defined below);

(h) a copy of the Amended and Restated Bylaws of the Company certified pursuant to the Secretary's Certificate;

(i) a copy of certain resolutions of the Board of Directors of the Company, adopted on July 13, 2011, and certain resolutions of the Deal Committee thereof, adopted on July 14, 2011, certified pursuant to the Secretary's Certificate;

(j) an executed copy of the certificate of David A. McDonald, Chief Financial Officer of the Company, dated the date hereof, a copy of which is attached as Exhibit A hereto (the "Company's Certificate");

(k) an executed copy of the certificate of Peter Graham, Assistant Secretary of the Company, dated the date hereof (the "Secretary's Certificate");

(l) a specimen certificate evidencing the common stock;

(m) copies of each of the Scheduled Contracts (as defined below);

(n) a copy of a certificate, dated July 13, 2011, and a bringdown verification thereof, dated the date hereof, from the Secretary of State of the State of Delaware, with respect to the Company's existence and good standing in the State of Delaware (the "Delaware Certificate"); and

(o) a copy of a certificate, dated July 12, 2011, and a bringdown verification thereof, dated the date hereof, from the Secretary of State of the State of New York as to the Company's authorization to do business in the State of New York (the "NY Certificate").

We have also examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates and receipts of public officials, certificates of officers or other representatives of the Company and others, and such other documents as we have deemed necessary or appropriate as a basis for the opinions set forth below.

In our examination, we have assumed the genuineness of all signatures including endorsements, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies. In making our examination of executed documents, we have assumed that the parties thereto, other than the Company, had the power, corporate or other, to enter into and perform all obligations thereunder and have also assumed the due authorization by all requisite action, corporate or other, and the execution and delivery by such parties of such documents and the validity and binding effect thereof on such parties. As to any facts material to the opinions expressed herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and others and of public officials, including the facts and conclusions set forth in the Company's Certificate.

We do not express any opinion with respect to the laws of any jurisdiction other than (i) the laws of the State of New York, (ii) the federal laws of the United

States of America, and (iii) the General Corporation Law of the State of Delaware (the "DGCL").

As used herein: "Organizational Documents" means those documents listed in paragraphs (g) and (h) above. "Scheduled Contracts" means those agreements or instruments described on Schedule II hereto. "Scheduled Orders" means those orders or decrees described on Schedule III hereto (no such orders or decrees are so described).

Based upon the foregoing and subject to the limitations, qualifications, exceptions and assumptions stated herein, we are of the opinion that:

1. Based solely on our review of the Delaware Certificate, the Company has been duly incorporated and is validly existing in good standing under the DGCL.

2. Based solely on our review of the NY Certificate, the Company is authorized to do business in the State of New York.

3. The Company has the corporate power and authority to execute and deliver the Underwriting Agreement and to consummate the transactions contemplated thereby.

4. The Underwriting Agreement has been duly authorized, executed and delivered by all requisite corporate action on the part of the Company under the DGCL.

5. Neither the execution and delivery by the Company of the Underwriting Agreement nor the consummation by the Company of the transactions contemplated thereby, including the issuance and sale of the Securities: (i) conflicts with the Organizational Documents, (ii) constitutes a violation of, or a default under, any Scheduled Contract or (iii) contravenes any Scheduled Order.

6. Neither the execution and delivery by the Company of the Underwriting Agreement nor the consummation by the Company of the transactions

contemplated thereby, including the issuance and sale of the Securities: (i) violates any law, rule, or regulation of the State of New York, the State of Delaware or the United States of America or (ii) requires the consent, approval, licensing or authorization of, or any filing, recording or registration with, any governmental authority under any law, rule or regulation of the State of New York, the State of Delaware or the United States of America except for those consent, approvals, licenses and authorizations already obtained and those filing, recordings and registrations already made.

7. The Securities have been duly authorized by all requisite corporate action on the part of the Company under the DGCL and, when the stock certificate is delivered to and paid for by you in accordance with the terms of the Underwriting Agreement, will be validly issued, fully paid and non-assessable and free and clear of any preemptive rights or any similar rights arising under the DGCL, the Organizational Documents or any Scheduled Contract.

8. The Company has authority to issue 70,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, par value $0.01 per share, and such authorized capital stock of the Company conforms as to legal matters to the description thereof contained in the Prospectus under the caption “Description of Capital Stock.”

9. The statements in the Preliminary Prospectus under the caption “Description of Capital Stock,” insofar as such statements purport to summarize provisions of the DGCL and the Organizational Documents, fairly summarize such provisions in all material respects.

10. The Company is not and, solely after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Prospectus Supplement, will not be an “investment company” as such term is defined in the Investment Company Act of 1940.

The opinions stated herein are subject to the following qualifications:

(a) except to the extent expressly stated in the opinions contained herein, we do not express any opinion with respect to any law, rule or regulation that is

applicable to any party to the Underwriting Agreement or the transactions contemplated thereby solely because such law, rule or regulation is part of a regulatory regime applicable to any such party or any of its affiliates as a result of the specific assets or business operations of such party or such affiliates;

(b) except to the extent expressly stated in paragraph 10 above, we do not express any opinion with respect to any securities, antifraud, derivatives or commodities laws, rules or regulations;

(c) we do not express any opinion with respect to whether the execution, delivery or performance by the Company of its obligations under the Underwriting Agreement will constitute a violation of, or a default under, any covenant, restriction or provision with respect to financial ratios or tests of any aspect of the financial condition or results of operations of the Company; and

(d) the opinion stated in paragraph 10 above is based solely on our discussions with the officers of the Company responsible for the matters discussed therein and our reliance on the representations and warranties of the Company contained in the Underwriting Agreement and the Company's Certificate.

This opinion is furnished only to you and is solely for your benefit in connection with the closing occurring today and the offering of the Securities, in each case pursuant to the Underwriting Agreement. Without our prior written consent, this opinion may not be used, circulated, quoted or otherwise referred to for any other purpose or relied upon by, or assigned to, any other person for any purpose, including any other person that acquires any Securities or that seeks to assert your rights in respect of this opinion (other than your successor in interest by means of merger, consolidation, transfer of a business or other similar transaction).

Very truly yours,

Schedule I

Incorporated Documents

1. Annual Report on Form 10-K of Delcath Systems, Inc. for the fiscal year ended December 31, 2010, filed with the Commission on March 8, 2011.

2. Quarterly Report on Form 10-Q of Delcath Systems, Inc. for the fiscal quarter ended March 31, 2011 (filed with the Commission on May 5, 2011).

3. Current Reports on Form 8-K of Delcath Systems, Inc., filed with the Commission on January 12, 2011 (Form 8-K/A), January 25, 2011, February 23, 2011, April 1, 2011, April 14, 2011, May 4, 2011, June 1, 2011, June 10, 2011 (Form 8-K/A), July 11, 2011, July 14, 2011 and July 19, 2011.

4. Definitive Proxy Statement on Schedule 14A of Delcath Systems, Inc., filed with the Commission on April 27, 2011.

Schedule II

Scheduled Contracts

1. Rights Agreement, dated October 30, 2001, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent

2. Form of Warrant to Purchase Shares of Common Stock dated June 15, 2009 issued pursuant to the Subscription Terms dated as of June 9, 2009 between the Company and Capital Ventures International

3. 2004 Stock Incentive Plan

4. 2009 Stock Incentive Plan

5. Form of Incentive Stock Option Agreement under the Company's 2004 Stock Incentive Plan

6. Form of Nonqualified Stock Option Agreement under the Company's 2004 Stock Incentive Plan

7. Form of Stock Grant Agreement under the Company's 2004 Stock Incentive Plan

8. Settlement Agreement, dated as of October 8, 2006, by and between the Company, Laddcap Value Partners LP, Laddcap Value Advisors LLC, Laddcap Value Associates LLC, any affiliate of the foregoing, and Robert B. Ladd

9. Modification Agreement dated April 9, 2007 between the Company, Laddcap Value Partners, LP, Laddcap Associates, LLC

10. Form of Warrant issued to investors in connection with the Company's September 2007 registered direct offering

11. Cooperative Research and Development Agreement dated as of March 29, 2007 between the Company and the National Cancer Institute

12. Form of Indemnification Agreement dated April 8, 2009 between the Company and members of the Company's Board of Directors

13. Separation and General Release Agreement dated as of July 5, 2009 between the Company and Richard L. Taney

14. Employment Agreement dated as of July 1, 2009 between the Company and Eamonn P. Hobbs

15. Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs

16. Employee Stock Option Grant Letter dated as of July 6, 2009 between the Company and Eamonn P. Hobbs

17. Lease with Option to Purchase between Fitzgerald Brothers Beverages, Inc., and the Company, dated as of September 1, 2009

18. Employment Agreement dated as of September 13, 2009 between Delcath Systems, Inc. and David A. McDonald

19. Employee Stock Option Grant Letter dated as of September 14, 2009 between the Company and David A. McDonald

20. Restricted Stock Agreement dated as of September 14, 2009 between the Company and David A. McDonald

21. Employment Agreement dated as of September 30, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D.

22. Employee Stock Option Grant Letter dated October 20, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D.

23. Restricted Stock Agreement dated as of October 20, 2009 between the Company and Krishna Kandarpa, M.D., Ph.D.

24. Employment Agreement dated as of November 2, 2009 between the Company and Agustin Gago

25. Lease between SLG 810 Seventh Lessee LLC and the Company dated as of February 5, 2010

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

27. Amendment No. 1 to Form of Employee Stock Option Grant Letter dated as of March 11, 2010 between the Company and Eamonn P. Hobbs

28. Employee Stock Option Grant Letter dated as of March 11, 2010 between the Company and Eamonn P. Hobbs

29. Employment Agreement dated as of April 16, 2010 between the Company and Peter Graham.

30. Amended and Restated Supply Agreement between B. Braun Medical Inc and the Company dated as of May 4, 2010

31. Employment Agreement dated as of May 5, 2010 between the Company and Barbra Keck

32. Underwriting Agreement between Canaccord Genuity, Inc. and the Company, dated as of August 16, 2010

33. Lease Modification, Extension and Additional Space Agreement between SLG 810 Seventh Lessee LLC and the Company dated as of September 27, 2010

34. License, Supply and Contract Manufacturing Agreement between Synerx Pharma, LLC and Bioniche Teoranta and the Company dated as of October 13, 2010.

35. Form of Restricted Stock Agreement under the Company's 2009 Stock Incentive Plan

36. Form of Restricted Stock Agreement (Non-Employee Directors) under the Company's 2009 Stock Incentive Plan

37. Form of Restricted Stock Agreement (Consultants) under the Company's 2009 Stock Incentive Plan

38. Form of Non-Statutory Stock Option Grant Letter under the Company's 2009 Stock Incentive Plan

39. Form of Non-Statutory Stock Option Grant Letter (Non-Employee Directors) under the Company's 2009 Stock Incentive Plan

40. Form of Non-Statutory Stock Option Grant Letter (Consultants) under the Company's 2009 Stock Incentive Plan

41. Interim Agreement, dated July 6, 2011, by and between Delcath Systems, Inc. and Eamonn Hobbs

Schedule III

Scheduled Orders

None.

EXHIBIT C

Form of Opinion of Intellectual Property Counsel

July , 2011

Jefferies & Company, Inc.
520 Madison Avenue
New York, New York 10022

Re: Delcath Systems, Inc.
Form of Intellectual Property Counsel Opinion

Dear Sirs:

Such counsel has examined information incorporated by reference in the Company's April 13, 2010 Registration Statement on Form S-3 (File No. 333-165677)(the "Registration Statement") and the Rule 424(b)(5) Prospectus Supplement dated July 14, 2011 (the "Prospectus Supplement") under the captions "Business - Intellectual Property and Other Rights," and "Risk Factors - Our success depends in large part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties" (collectively, the "Designated Intellectual Property Provisions").

1. All patents and trademarks and pending patent and trademark applications ("Patents and Trademarks") that are owned by the Company are listed on IP Schedule A, attached hereto. Information concerning the application number, filing data and status of the Patents and Trademarks also is set forth in IP Schedule A, based upon our knowledge.

2. Except as set forth below, to our knowledge, the statements in the above identified Designated Intellectual Property Provisions, insofar as such statements pertain to Intellectual Property matters or purport to describe or summarize applicable provisions of Intellectual Property laws, accurately and fairly represent the information referred to therein.

3. To our knowledge, (A) there are no rights of parties other than the Company to any of the Patents and Trademarks listed on IP Schedule A, (B) there are no pending or threatened actions, suits, proceedings or claims by others challenging the Company's rights to or in any such Patents and Trademarks and (C) there are no pending or threatened actions, suits, proceedings or claims by others that the Company is infringing or otherwise violating any patent, trademark, or trade secret rights of others.

4. To our knowledge, the Company has complied with the examination requirements of the United States Patent and Trademark Office ("USPTO") duty of candor and disclosure for each of the United States Patents and Trademarks listed in IP Schedule A. No fact has come to our attention that causes us to question the enforceability of any of the Patents and Trademarks listed on IP Schedule A, or to question the validity of any of the Patents and Trademarks listed on IP Schedule A.

5. To our knowledge, there are no legal or governmental proceedings relating to the Company's patent and trademark rights, other than normal *ex parte* USPTO examination proceedings and similar proceedings (including, without limitation, opposition proceedings, in other jurisdictions). To our knowledge, all issued patents and trademarks listed on IP Schedule A have been lawfully issued.

6. To our knowledge, and except as described in documents filed with the Securities and Exchange Commission, there are no agreements with third parties relating to the acquisition, licensing and/or transfer of Intellectual Property rights which have or are anticipated to have a material impact on the Company's existing or future business, including license agreements, joint venture agreements, marketing and/or distribution agreements or other collaboration agreements that are not currently in effect or that will be expiring soon, nor to our knowledge has there been any notice of termination on or other act indicating a desire to terminate any of the aforesaid agreements.

7. To our knowledge, there are no facts that prevent the Company from using its Intellectual Property and know-how to conduct its business or from enforcing its rights to its Patents and Trademarks.

Nothing has come to our attention which causes us to believe that the Designated Intellectual Property Provisions, at the time the Registration Statement became effective and at all times subsequent thereto up to and on the date hereof, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

Very truly yours,

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
I. U.S. PATENT NO. 5,069,662 (020800)

Filing Date: October 21, 1988
Patent Issuance Date: December 3, 1991
Projected Expiration Date (not including any applicable patent term adjustments / extensions): December 3, 2008 (expired)
Title: CANCER TREATMENT
Ownership Status: Delcath Systems, Inc. is assignee
Litigation Status: None.

Status Of Foreign Counterparts:

Country	Patent/Application Number	Status
Canada	CA 1333872	Issued patent - expires January 10, 2012
Japan	JP 2831056 / JP 2193676	Issued patent - expired
Austria	AT 121952	Issued patent - expired
Belgium	EP 0364799	Issued patent - expired
France	EP 0364799	Issued patent - expired
Germany	DE 68922456	Issued patent - expired
Greece	EP 0364799	Issued patent - expired
Luxembourg	EP 0364799	Issued patent - expired
Netherlands	EP 0364799	Issued patent - expired
Spain	ES 2075022	Issued patent - expired
Sweden	EP 0364799	Issued patent - expired
Switzerland	EP 0364799	Issued patent - expired
UK	UK 364 799	Issued patent - expired

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
II. U.S. PATENT NO. 5,411,479 (020809)

Filing Date: April 30, 1993
Patent Issuance Date: May 2, 1995
Projected Expiration Date (not including any applicable patent term adjustments / extensions): May 2, 2012
Title: CANCER TREATMENT AND CATHETER FOR USE IN TREATMENT
Ownership Status: Delcath Systems, Inc. listed as assignee.

Foreign Counterparts:

Country	Patent/Application Number	Status
Foreign counterparts are the same as listed in I. above		

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL

III. U.S. PATENT NO. 5,817,046 (020400)

Filing Date: July 14, 1997
Patent Issuance Date: October 6, 1998
Projected Expiration Date (not including any applicable patent term adjustments / extensions): July 14, 2017
Title: APPARATUS AND METHOD FOR ISOLATED PELVIC PERFUSION
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

…

Foreign Counterparts:

Country	Patent/Application Number	Status
Canada (020402)	CA 2297080	Issued - in force
European Patent Office (020403)	EP 1027094	Issued as EPO patent 1027094. Nationalized in Austria, Belgium, United Kingdom, Switzerland, Spain, France, Germany, Ireland, Italy, the Netherlands, Portugal, Sweden

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL

IV. U.S. PATENT NO. 5,893,841 (020200)

Filing Date: August 30, 1996
Patent Issuance Date: April 13, 1999
Projected Expiration Date (not including any applicable patent term adjustments / extensions: August 30, 2016
Title: BALLOON CATHETER WITH OCCLUDED SEGMENT BYPASS
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

Foreign Counterparts:

Country	Patent/Application Number	Status
Japan	JP 4039698	Issued - in force.
Japan	JP 2007-200716	Pending
Canada	CA 2264559	Pending
Belgium	EP 0936933	Issued - patent in force.
France	EP 0936933	Issued - patent in force.
Germany	DE 69735487	Issued - patent in force.
Italy	EP 0936933	Issued - patent in force.
Sweden	EP 0936933	Issued - patent in force.
United Kingdom	EP 0936933	Issued - patent in force.

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
V. U.S. PATENT NO. 5,897,533 (020600)

Filing Date: September 2, 1997
Patent Issuance Date: April 27, 1999
Projected Expiration Date (not including any applicable patent term adjustments / extensions): September 2, 2017
Title: CATHETER FLOW AND LATERAL MOVEMENT CONTROLLER
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

Foreign Counterparts: None active

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
VI. U.S. PATENT NO. 5,919,163

Filing Date: July 14, 1997
Patent Issuance Date: July 6, 1999
Projected Expiration Date (not including any applicable patent term adjustments / extensions): July 14, 2017
Title: CATHETER WITH SLIDABLE BALLOON
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

Foreign Counterparts: None Active

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
VII. U.S. PATENT NO. 6,186,146 (020301)

Filing Date: January 13, 1997 (claiming priority as CIP of 08/706,186 filed August 30, 1996)
Patent Issuance Date: February 13, 2001
Projected Expiration Date (not including any applicable patent term adjustments / extensions): August 30, 2016
Title: CANCER TREATMENT METHOD
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

Foreign Counterparts: None Found

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL

VIII. U.S. PATENT NO. 7,022,097

Filing Date: May 9, 2003
Patent Issuance Date: April 4, 2006
Projected Expiration Date (not including any applicable patent term adjustments / extensions) : May 9, 2023
Title: METHOD FOR TREATING GLANDULAR DISEASES AND MALIGNANCIES
Ownership Status: Delcath Systems, Inc. listed as assignee.
Litigation Status: None.

Foreign Counterparts:

Country	Patent/Application Number	Status
Canada	CA 2524858	Pending — Request for Examination filed
European Patent Office	EP 10170460.9	Pending — Divisional application filed July, 2010 based on abandoned EP 1622674

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL
IX. PCT PATENT APPLICATION (US as receiving office) NO. PCT/US09/63744

Filing Date: November 9, 2009.
Patent Issuance Date: N/A
Title: SYSTEMS AND METHODS FOR HOMEOSTATICALLY TREATING ORGAN DISEASE USING LOCAL DELIVERY OF THERAPEUTIC AGENTS
Projected Expiration Date (not including any applicable patent term adjustments / extensions): 2020 (Chinese utility model)
Ownership Status: Delcath Systems, Inc. as assignee.
Litigation Status: None

Foreign Counterparts:

Country	Patent/Application Number	Status
China	"CATHETER AND APPARATUS COMPRISING SUCH A CATHETER" (filed January 11, 2010, claiming priority from PCT)	Issued as Chinese Model Utility Patent No. ZL 2010 2000 2009.3

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL

TRADEMARK	COUNTRY	GOODS / SERVICES	CLASS(ES)	STATUS	APP. NO.	REG. NO.
CHEMOFUSE	European Union	Drug delivery systems	10	Registered	9544297	9544297
CHEMOFUSE	U.S.A.	Drug delivery systems	10	Pending	85/172,818	
CHEMOSAT	Argentina	Drug delivery systems	10	Pending	3006313	
CHEMOSAT	Australia	Drug delivery systems	10	Registered	1354961	1033246
CHEMOSAT	China	Drug delivery systems	10	Pending	A0018997	1033246
CHEMOSAT	Colombia	Drug delivery systems	10	Registered	1077052	415377
CHEMOSAT	European Union	Drug delivery systems	10	Registered	A0018997	1033246
CHEMOSAT	India	Drug delivery systems	10	Pending	1935212	
CHEMOSAT	Korea (South)	Drug delivery systems	10	Pending	A0018997	1033246
CHEMOSAT	Mexico	Drug delivery systems	10	Registered	1072333	1187556
CHEMOSAT	Taiwan	Medical apparatus, medical instruments for drug delivery systems	10	Pending	99009554	
CHEMOSAT	U.S.A.	Drug delivery systems	10	Pending	77/944,997	
CHEMOSATURATION	Argentina	Drug delivery systems	10	Pending	3006314	
CHEMOSATURATION	Australia	Drug delivery systems	10	Registered	A0018998	1033711
CHEMOSATURATION	Brazil	Drug delivery systems	10	Pending	830632321	
CHEMOSATURATION	China	Drug delivery systems	10	Pending	A0018998	
CHEMOSATURATION	Colombia	Drug delivery systems	10	Registered	10077050	415376
CHEMOSATURATION	India	Drug delivery systems	10	Pending	1935211	
CHEMOSATURATION	Japan	Drug delivery systems	10	Registered	A0018998	1033711
CHEMOSATURATION	Korea (South)	Drug delivery systems	10	Registered	A0018998	1033711
CHEMOSATURATION	Mexico	Drug delivery systems	10	Registered	1072332	1187555
CHEMOSATURATION	Taiwan	Medical Apparatus, medical instruments for drug delivery systems	10	Pending	99009555	
CHEMOSATURATION	U.S.A.	Drug delivery systems	10	Pending	77/945,002	
DELCATH	European Union	Drug delivery systems	10	Registered	A0024132	1075265

DELCATH SYSTEMS, INC.
INTELLECTUAL PROPERTY OPINION LETTER — EXHIBIT A
PRIVILEGED AND CONFIDENTIAL

DELCATH	U.S.A.	Class 10: Double balloon catheter system comprised primarily of catheters Class 42: Medical services, namely, cancer treatment	10, 42	Registered	76/266,056	2.609.452
DELCATH	U.S.A.	Pharmaceutical products for the prevention and treatment of cancer	5	Pending	85/288,586	
DELCATH	U.S.A.	Drug delivery systems	10	Pending	85/288,673	
DELKERAN	Argentina	Pharmaceutical preparations for use in chemotherapy	5	Pending	3011124	
DELKERAN	Australia	Pharmaceutical preparations for use in chemotherapy	5	Registered	A0018996	1354960
DELKERAN	Brazil	Pharmaceutical preparations for use in chemotherapy	5	Pending	830678670	
DELKERAN	China	Pharmaceutical preparations for use in chemotherapy	5	Registered	A0018996	1033245
DELKERAN	Colombia	Pharmaceutical preparations for use in chemotherapy	5	Registered	10025071	412426
DELKERAN	India	10- Pharmaceutical preparations for use in chemotherapy	10	Registered	1935213	1000910
DELKERAN	Japan	Pharmaceutical preparations for use in chemotherapy	5	Pending	A0018996	1033245
DELKERAN	Korea (South)	Pharmaceutical preparations for use in chemotherapy	5	Registered	A0018996	1033245
DELKERAN	Mexico	Pharmaceutical preparations for use in chemotherapy	5	Pending	1075546	
DELKERAN	Taiwan	Pharmaceutical preparations for use in chemotherapy	5	Registered	99011209	1431946
DELKERAN	U.S.A.	Pharmaceutical preparations for use in chemotherapy	5	Pending	77/947,336	
INTENZIF	European Union	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Registered	9544487	9544487

INTENZIF	U.S.A.	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Pending	85/181,602	
ITENZIF	European Union	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Pending	10014165	
ITENZIF	U.S.A.	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Pending	85/320,279	
ISO-FUSE	Argentina	Drug delivery systems	10	Pending	2982807	
ISO-FUSE	Australia	Drug delivery systems	10	Pending	A0018891	
ISO-FUSE	Brazil	Drug delivery systems	10	Pending	830540040	
ISO-FUSE	China	Drug delivery systems	10	Pending	A0018891	
ISO-FUSE	Colombia	Drug delivery systems	10	Pending	10024515	
ISO-FUSE	European Union	Drug delivery systems	10	Registered	A0018891	1033135
ISO-FUSE	India	Drug delivery systems	10	Registered	1929176	993908
ISO-FUSE	Japan	Drug delivery systems	10	Pending	A0018891	
ISO-FUSE	Mexico	Drug delivery systems	10	Registered	1071313	1187552
ISO-FUSE	Taiwan	Medical apparatus, medical instruments for drug delivery systems	10	Registered	99009131	1426959
ISO-FUSE	U.S.A.	Drug delivery systems	10	Pending	77/818,131	
MELMISAT	European Union	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Registered	9544552	9544552

MELMISAT	U.S.A.	Class 5: Pharmaceutical products for the treatment of cancer Class 42: Medical research services in the field of cancer	5, 42	Pending	85/181,614	
PHP	U.S.A.	Drug delivery systems	10	Registered	77/529,005	3880422
THE DELCATH PHP SYSTEM	U.S.A.	Drug delivery systems	10	Registered	77/529,348	3926021

EXHIBIT D

Form of Regulatory Counsel Opinion

July , 2011

JEFFERIES & COMPANY, INC.
520 Madison Avenue
New York, New York 10022

Re: Delcath Systems, Inc.

Ladies and Gentlemen:

This letter is furnished to you pursuant to Section 6(f) of the Underwriting Agreement dated July 14, 2011 (the "Underwriting Agreement") between you and Delcath Systems, Inc., a company organized and existing under the laws of the State of Delaware (the "Company"), relating to the issuance and sale by the Company of 5,000,000 shares (the "Firm-Shares") of the Company's common stock, par value $0.01 per share, and up to an additional 750,000 shares of the Company's common stock at your option to cover over-allotments (together with the Firm Shares, the "Shares") pursuant to the terms of the Underwriting Agreement. Capitalized terms used herein that are defined in the Underwriting Agreement shall have the meanings set forth in the Underwriting Agreement, unless otherwise defined herein.

We have acted in the limited role of special United States Food and Drug Administration ("FDA") and European Union ("EU") regulatory counsel to the Company with respect to FDA pharmaceutical and EU medical devices regulatory matters in connection with the Company's offering of securities in the United States ("special FDA and EU counsel"). We have not been retained or engaged by the Company to perform, nor have we performed, any review of any information, other than the statements specifically listed below, for purposes of this letter. We have not been retained or engaged by the Company to perform, nor have we performed, any review of any other information contained in the Registration Statement, Preliminary Prospectus, Time of Sale Prospectus and Prospectus. Additionally, we have not been retained or engaged to provide advice in respect of United States securities laws or the rules or regulations of the Securities and Exchange Commission thereunder (the "Rules"), nor have we been retained or engaged by the Company to provide advice as to whether any information or any statement, opinion or other writing is required under the United States securities laws or the Rules to be filed with or submitted to, the Securities Exchange Commission, and the matters addressed herein should not be construed as such advice, except as set forth herein.

We have reviewed the following statements in the Preliminary Prospectus, Time of Sale Prospectus and Prospectus under the captions "Regulatory Environment – International Regulation;" "Regulatory Environment – United States Regulation;" "Risks Related to FDA and

Foreign Regulatory Approval – Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations;" "Risks Related to FDA and Foreign Regulatory Approval – While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval;" "Risks Related to FDA and Foreign Regulatory Approval – The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system by the FDA for use in the United States;" "Risks Related to FDA and Foreign Regulatory Approval – We have obtained the right to affix the CE Mark for the Delcath chemosaturation system as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with the Delcath chemosaturation system, our ability to commercialize the Delcath chemosaturation system in the EEA will be significantly limited;" "Risks Related to FDA and Foreign Regulatory Approval – Even if we obtain regulatory approval for the Delcath chemosaturation system in the United States, our ability to market the Delcath chemosaturation system would be limited to those uses that are approved;" "Risks Related to FDA and Foreign Regulatory Approval – If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the Delcath chemosaturation system for other indications;" "Risks Related to FDA and Foreign Regulatory Approval —While we have received approval of our clinical trial protocol from the FDA under a SPA, our failure to execute the clinical trial according to the agreed upon trial protocol may result in loss of FDA approval and invalidation of our clinical trials." "Risks Related to FDA and Foreign Regulatory Approval – We rely on third parties to conduct certain of the clinical trials for the Delcath chemosaturation system, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system;" and "Risks Related to Manufacturing, Commercialization and Market Acceptance of the Delcath Chemosaturation System – We purchase components for the Delcath chemosaturation system from third parties, some of which are sole-source suppliers" (collectively, the "**Regulatory Portion**").

The purpose of our engagement as special FDA and EU counsel was to review the Regulatory Portion disclosure and not to establish or confirm factual matters. Therefore, we have not independently verified, and accordingly are not confirming and assume no responsibility for, the accuracy, completeness or fairness of the statements relating to factual matters contained in the Preliminary Prospectus, Time of Sale Prospectus and Prospectus, or whether or not the Company is in compliance with the FDA Laws (as defined below) and EU Laws (as defined below). We are familiar with the United States Federal Food, Drug, and Cosmetic Act (the "**FFDC Act**") set forth at 21 U.S.C. § 301 et seq., regulations promulgated pursuant to the authority of the FFDC Act, and the enforcement of the FFDC Act and its regulations by the **FDA** (for purposes of this opinion referred to collectively as the "**FDA Laws**"); and with EU Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended (the "**EU Medical Devices Directive**"), and the European Commission guidance and interpretative documents on medical devices (the "**EU Medical Devices Guidelines**") (for purposes of this opinion referred to collectively as the "**EU Laws**"). Our opinion is expressed only with respect to the FDA Laws and EU Laws. We express no opinion as to whether the laws of any jurisdiction other than those

identified above apply, and we express no opinion to the extent the laws of any jurisdiction other than those identified above are applicable to the subject matter hereof.

In connection with our review of the statements in the Regulatory Portion, we have requested from the Company all documents and information material to such statements as they relate to the FDA Laws and EU Laws, and have received, reviewed, and relied upon only (a) documents provided to us by the Company which the Company identified as responsive to requests for all material documents pertaining to the Regulatory Portion, and (b) representations made to us and others during discussions with Mr. Peter Graham and Mr. John Purpura during the period June 1, 2011 – July 12, 2011. We have assumed with your approval the accuracy and completeness of all statements of fact relating to the Company and the status of its products, and you have not asked us to make, and we have not made, any independent investigations with regard to such matters for purposes of rendering the opinion herein. We have also assumed the accuracy and completeness of all documents and records that we have reviewed, the genuineness of all signatures, the authenticity of the documents submitted to us as originals, and the conformity to authentic original documents of all documents submitted to us as certified, conformed or reproduced copies. Further, we have not independently verified, nor do we take responsibility for, or are we in any way addressing, any statements of belief attributable to the Company.

On the basis of the foregoing, in reliance thereon and with the foregoing qualifications, we are of the opinion that, insofar as the statements in the Regulatory Portion constitute summaries of the FDA Laws and EU Laws, the Regulatory Portion contains accurate summaries in all material respects of the provisions purported to be summarized therein.

This opinion is rendered solely for your benefit in connection with the closing on the date hereof of the purchase by the Underwriter of the Firm Shares pursuant to the Underwriting Agreement. This opinion may not be used or relied upon by you for any other purpose, or furnished to, disclosed to, assigned to, quoted to, filed with, or relied upon by any other person, firm, governmental agency or other entity for any purpose (including any person, firm or other entity that acquires Shares from you), in whole or in part, without our express prior written consent, which may be granted or withheld in our sole discretion. This opinion is limited to the matters stated herein, and no opinion or belief is implied or may be inferred beyond the matters expressly stated herein. This letter speaks only as to law and facts in effect or existing as of the date hereof and we undertake no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in any law that may hereafter occur.

Sincerely,

SUMMARY

This summary highlights selected information more fully described elsewhere in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this prospectus supplement, the accompanying prospectus, any free writing prospectus and the documents incorporated by reference herein and therein carefully, especially the risks of investing in our common stock discussed in "Risk Factors" below and the other risks described in the incorporated documents.

In this prospectus supplement, except as otherwise indicated, "Delcath," "Delcath Systems," "we," "our," and "us" refer to Delcath Systems, Inc., a Delaware corporation and its subsidiary. "Delcath" is our registered United States trademark.

Company Overview

We are a development stage, specialty pharmaceutical and medical device company focused on oncology, initially cancers in the liver. Since our inception, we have directed our research efforts towards the development and clinical study of the Delcath chemosaturation system.

The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapy agents, currently melphalan hydrochloride, or melphalan, directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the protocol's design, execution, and analysis under a Special Protocol Assessment, or SPA. A SPA is an evaluation by the U.S. Food and Drug Administration, or FDA, of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in a new drug application, or NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. We conducted our Phase III trial under a SPA.

In February 2010, we concluded a Phase III clinical trial for the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver, which demonstrated a statistically significant improvement in hepatic progression-free survival, or hPFS, compared to the best alternative care. Our Phase III trial successfully met the study's primary endpoint of extended hPFS, demonstrating that the Delcath chemosaturation system with melphalan patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the best alternative care control arm. This reflects a 144-day prolongation of hPFS over that of the best alternative care control arm, with less than half the risk of progression and/or death in the Delcath chemosaturation system with melphalan group compared to the best alternative care control group. In addition, we recently completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer.

Based on the Phase III results, we submitted our Section 505(b)(2) NDA, to the FDA in December 2010, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, we received a Refusal to File RTF letter, or RTF, from the FDA for the NDA. The FDA will issue an RTF if it determines upon an initial review that the

NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. At this time, the FDA has not requested additional studies to be conducted. We have had subsequent communications with the FDA, including a meeting in early April 2011 to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011.

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath chemosaturation system. The right to affix the CE mark allows us to market and sell the Delcath chemosaturation system in the European Economic Area, or EEA. In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

We believe the Delcath chemosaturation system may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in the EEA. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to establish a European headquarters within the EEA and utilize third-party contract sales organizations, or CSOs, and a direct sales force in the United Kingdom, Germany and the Netherlands and distributors in France, Italy and Spain. We also intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in these countries in order to develop key opinion thought leadership and foster initial market acceptance.

Advantages of the Delcath Chemosaturation System

Limited effective treatment options are currently available for liver cancer and they are generally associated with significant side effects and even death. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgically isolated perfusion and liver transplant. We believe the Delcath chemosaturation system may address the critical shortcomings of traditional liver cancer treatments based on the results of our Phase I, Phase II and Phase III trials:

- *Allows Higher Dosing*—Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of delivering up to ten times more of the chemotherapy agent to the treated region than traditional delivery methods. In our clinical studies on patients with metastatic melanoma it was shown that higher dosing led to significantly improved disease control in the liver.
- *Controls Toxicities*—Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of extracting on average 72% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.

- *Minimally Invasive and Repeatable*—The Delcath chemosaturation system allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter than surgical resection.
- *Treats the Entire Liver*—By introducing the chemotherapeutic agent into the arterial blood supply feeding the liver, the Delcath chemosaturation system perfuses the entire liver with chemotherapy, treating both tumors that are visible as well as "micro metastases" that cannot be detected by imaging.

Strategy

We believe the Delcath chemosaturation system represents a potentially important new treatment option for cancers in the liver. We are seeking to establish the Delcath chemosaturation system as the standard regional therapy technique for the treatment of melanoma liver metastases and other liver cancer histologies.

We also intend to develop the system for use with other chemotherapeutic agents, as well as other drug compounds. We are continuing our research and development efforts with respect to other chemotherapeutic agents and the treatment of other types of cancer and will need to conduct additional clinical trials and seek approval for escalating doses of anti-cancer agents, including melphalan, for use with the Delcath chemosaturation system. As part of our development efforts, we intend to pursue U.S. pharmaceutical partners to co-develop and fund additional indications for the Delcath chemosaturation system.

Our strategy includes the following elements:

- *Commercialize the Delcath Chemosaturation System in the European Economic Area.* We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly market the Delcath chemosaturation system in certain markets and enter into agreements with third-party distributors in others.
- *Leverage the CE Mark to Commercialize the Delcath Chemosaturation System in Other Countries*. We believe the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the United States, including but not limited to Argentina, Australia, Brazil, China, Colombia, Dubai, Hong Kong, Japan, Jordan, Malaysia, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Thailand and Turkey. It is our intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath chemosaturation system, where appropriate.
- *Obtain FDA Approval for Use of the Delcath Chemosaturation System in Combination with Melphalan to Treat Metastatic Melanoma in the Liver*. Based on management's current understanding of the issues raised in the RTF, we have begun to take action to address the FDA's concerns, and currently plan to resubmit our NDA to the FDA by December 31, 2011.
- *Commercialize the Delcath Chemosaturation System in the United States.* If we obtain FDA approval of our NDA, we intend to market the Delcath chemosaturation system with melphalan in the United States through our own sales force and focus our initial marketing efforts on major cancer centers beginning with those hospitals that participated in our Phase III clinical trial.
- *Establish Strategic Alliances.* We intend to pursue strategic partners to develop certain Asian markets including China, Korea and Japan. In the United States, we intend to pursue pharmaceutical partners to co-develop and fund other indications for the Delcath chemosaturation system.
- *Obtain Approval to Market the Delcath Chemosaturation System in the United States for the Treatment of Other Cancers in addition to Metastatic Melanoma in the Liver.* We recently concluded a multi-arm Phase II trial to evaluate the Delcath chemosaturation system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, primary liver cancer and melanomas in the liver that received certain prior regional treatment with melphalan. Upon successful conclusion of the related clinical trials, we intend to apply for regulatory approval of additional indications.

- *Expand the Application of the Delcath Chemosaturation System.* We intend to evaluate melphalan and other drug candidates for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions.

Sales and Marketing

Having obtained the right to affix the CE Mark in Europe, we plan to market and sell the Delcath chemosaturation system in the EEA. The EEA consists of the 27 member countries of the European Union as well as Lichtenstein, Iceland, and Norway. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath chemosaturation system. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system has received authorization to affix the CE Mark as a device only. Melphalan is currently approved in 14 member states of the EEA, including the six countries we are initially targeting. Physicians must separately obtain melphalan for use with the Delcath chemosaturation system.

In the United States, if granted FDA approval, our intention is to market the system ourselves focusing our initial marketing efforts on the over fifty National Cancer Institute, or NCI, designated cancer centers in the United States, beginning with the hospitals which participated in the Phase III clinical trial. We plan to focus our efforts on three distinct groups of medical specialists:

- surgical oncologists who administer the Delcath chemosaturation system;
- medical oncologists who have initial responsibility for cancer patients; and
- interventional radiologists who are physicians specialized in working with catheter-based systems and who will also administer the Delcath chemosaturation.

We intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals.

Strategic Alliances

We plan to seek one or more corporate partners in other markets outside the United States, including Asia where we intend to pursue strategic partners to develop markets in China, Korea and Japan. Asia represents a potentially large market for the Delcath chemosaturation system, accounting for approximately 80% of the world’s liver cancer patients. We also intend to leverage our CE Mark in order to expedite approval in select countries in Latin America and South America. We believe distribution or corporate partnering arrangements in select markets internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target.

We believe that the Delcath chemosaturation system may have broader applicability, including using other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. As such, we also intend to pursue U.S. pharmaceutical partners to co-develop and fund possible additional indications for the Delcath chemosaturation system.

Risks of Investing

Investing in our securities involves risks. Potential investors are urged to read and consider the risk factors relating to an investment in the common stock set forth under “Risk Factors” in this prospectus supplement and the accompanying prospectus and those described in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC and incorporated by reference in this prospectus supplement and the accompanying prospectus as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus.

Corporate Information

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 810 Seventh Avenue, Suite 3505, New York, New York 10019. Our telephone number is (212) 489-2100. Our website address is http://www.delcath.com. Information contained in our website is not a part of this prospectus supplement or the accompanying prospectus.

REGULATORY ENVIRONMENT

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

International Regulation

In order for our products to be marketed and sold in Asia, Europe, or other foreign jurisdictions, we must obtain the required regulatory approvals or clearances and comply with the extensive regulations regarding safety, manufacturing processes and quality requirements of the respective countries. These regulations, including the requirements for approvals to market, and the various regulatory frameworks may differ. In addition, there may be foreign regulatory barriers other than approval or clearance.

In the EEA, the Delcath chemosaturation system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the Delcath chemosaturation system are governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the Delcath chemosaturation system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments. For Class III medical devices, such as the Delcath chemosaturation system, before issuing a certification indicating compliance with the essential requirements, a Notified Body will typically audit a manufacturer’s quality system for the design, manufacture, and final inspection of the medical devices, and examine the specific design dossier of the products covered by the conformity assessment. Based on this certification, manufacturers can complete an EC Declaration of Conformity which allows them to affix the CE mark to their products.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer’s behalf

with regard to the manufacturer's obligations under the EU Medical Devices Directive. We have appointed such a representative, although we are in the process of establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

On April 13, 2011, we obtained the required certification from Lloyd's Register Quality Assurance, or LRQA, a UK notified body, for the Delcath chemosaturation system with the following labeled indication: intra-arterial administration of the chemotherapeutic agent melphalan hydrochloride to the liver with additional extracorporeal flirtation of the venous blood return. Based on this certification, we can complete an EC Declaration of Conformity and affix the CE mark to the Delcath chemosaturation system.

Although the Delcath chemosaturation system is CE marked, the provisions of the EU Medical Devices Directive are implemented into the national laws of the Member States of the European Union, which may impose additional conditions on the commercialization of medical devices within their territory, including, for example, language used on the device's labeling. These Member State national laws are enforced by the respective competent authorities of each Member State, which may differ on the interpretation of the provisions of the EU Medical Device Directive as implemented into their national laws. Therefore, complying with the regulations of one Member State does not automatically ensure compliance in other Member States.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the European Union must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action, or FSCA. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include, device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission is currently reviewing the medical devices legislative framework with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. These adopted or expected regulatory changes may adversely affect our business, financial condition and results of operations or restrict our operations.

United States Regulation

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations. The Delcath chemosaturation system is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the center for Drug Evaluation and Research, or CDER, has primary jurisdiction over its pre-market development and review. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials.

Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- *Phase I Clinical Trials.* Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- *Phase II Clinical Trials.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- *Phase III Clinical Trials.* These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- *Phase IV Clinical Trials.* The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase IV clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Prior to initiating our Phase III clinical trial, we submitted a proposal for the design, execution and analysis under a SPA, and we conducted our Phase III trial under a SPA.

New Drug Applications. The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

In December 2010, we submitted our NDA for the Delcath chemosaturation system under Section 505(b)(2) of the FFDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from

studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products, such as melphalan. Melphalan, the drug we are initially seeking to have approved for use with the Delcath chemosaturation system, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we used in our Phase III clinical trial. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Delcath chemosaturation system delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that which is currently approved, we will be seeking a revised label of melphalan for use with the Delcath chemosaturation system through its Section 505(b)(2) NDA. The clinical trials were designed to provide the necessary clinical data to support this required labeling change.

In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue a Refusal to File letter, or RTF, if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. In February 2011, we received an RTF from the FDA for the NDA. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. We have had subsequent communications with the FDA, including a meeting in early April to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011 which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA.

Upon resubmission of our application, the FDA will again perform an initial review to assess whether the NDA is sufficiently complete to warrant a substantive review. If the FDA agrees to formally file the application, it will issue a Prescription Drug User Fee Act, or PDUFA, action date. If the drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs for the condition, the sponsor may be subject to a Fast Track designation. The Fast Track program is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Under the program, the sponsor of a new drug may request that the FDA designate the drug for a specific indication as a fast track product concurrent with or after the IND is filed for the product candidate, and the FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The Delcath chemosaturation system has received a Fast Track designation. A drug that receives Fast Track designation may be eligible for more frequent meetings with FDA to discuss the drug's development; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials; eligibility for accelerated approval, i.e., approval of an effect on a surrogate, or substitute endpoint; and rolling review, meaning the sponsor may submit its NDA in sections rather than wait until the entire NDA is complete, among others. Most drugs with Fast Track designation are likely to be considered appropriate to receive a Priority Review. In 1992, under PDUFA, the FDA created a two-tiered system of review times – Standard Review and Priority Review. Standard Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies with a goal of completing the FDA review of the NDA within a ten-month time frame. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months. We intend to request a Priority Review in our resubmitted NDA to the FDA. We cannot guarantee that our application for approval of the Delcath chemosaturation system will receive a Priority Review, or that if Priority Review is received, that the review or approval will be faster than conventional FDA procedures or that FDA will ultimately grant approval.

Orphan Drug Exclusivity. Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to

drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting. The FDA has granted us four orphan drug designations. In November 2008, the FDA granted us two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted us an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted us an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. If the Delcath chemosaturation system is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. The Delcath chemosaturation system, if approved by the FDA, may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw approval of the NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers’ communications regarding off-label use. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indications and we could be subject to enforcement action for off-label marketing.

RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this prospectus supplement and the accompanying prospectus before deciding whether to purchase our common stock. In addition, you should carefully consider, among other things, the matters discussed under "Risk Factors" and "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2010 and in our Quarterly Report on Form 10-Q for the period ended March 31, 2011, and in other documents that we subsequently file with the Securities and Exchange Commission, all of which are incorporated by reference. The risks and uncertainties described below and incorporated by reference are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment. This prospectus supplement, the accompanying prospectus and the incorporated documents also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See "Disclosure Regarding Forward-Looking Statements."

Risks Related to Our Business and Financial Condition

If we are unable to develop the Delcath chemosaturation system, obtain regulatory approval outside the EEA or market and sell the system, we will not generate operating revenue or become profitable.

The Delcath chemosaturation system, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs, is our only product. Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of this product and currently we have only developed this system for the treatment of cancers in the liver with melphalan. If the Delcath chemosaturation system with melphalan fails as a commercial product, we have no other products to sell. In addition, since the Delcath chemosaturation system is currently only authorized for marketing in the EEA, if we are unsuccessful in commercializing the product in the EEA and the Delcath chemosaturation system is not approved in the United States and elsewhere, we will have no other means of generating revenue.

Continuing losses may exhaust our capital resources.

As of March 31, 2011, we had $39.3 million in cash, cash equivalents and certificates of deposit. We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. We expect to continue to incur losses while generating minimal revenues over the next year. From our inception on August 5, 1988 through March 31, 2011, we have incurred cumulative net losses of approximately $116.5 million. For the three months ended March 31, 2011 and years ended December 31, 2010, 2009 and 2008, we incurred net losses of approximately $1.9 million, $46.7 million, $22.1 million and $6.9 million, respectively, with these amounts being effected by derivative accounting related to warrants as described in our Annual Reports on Form 10-K for the years ended December 31, 2010, 2009 and 2008. To date, we have funded our operations through a combination of private placements and public offerings of our securities. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of the Delcath chemosaturation system with melphalan or any other versions of the system.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to commercialize the Delcath chemosaturation system, resubmit our NDA to the FDA or conduct future development and clinical trials.

We may require additional financing to commercialize our product in the EEA and any other markets where we receive approval for our system, to resubmit our NDA seeking U.S. marketing approval or seek other approvals and to conduct future development and clinical trials. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to sell the Delcath chemosaturation system commercially, obtain regulatory approvals or complete our trials.

Our liquidity and capital requirements will depend on numerous factors, including:

- our research and product development programs, including clinical studies;
- the timing and costs of our various U.S. and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, submissions for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath chemosaturation system is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the CDER has primary jurisdiction over its pre-market development and review.

We are not permitted to market the Delcath chemosaturation system in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;

- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is ten months for a standard application and six months for a priority review application. The FDA's review goals are subject to change and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted to FDA around the same time period. The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. Failure to obtain or delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current Delcath chemosaturation system or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the Delcath chemosaturation system as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with the Delcath chemosaturation system, our ability to commercialize the Delcath chemosaturation system in the EEA will be significantly limited.

In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. To the extent that our promotion of the Delcath chemosaturation system is found to be outside the scope of our approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize the Delcath chemosaturation system in the EEA.

Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable melphalan label with respect to some indications in some Member States of the EEA where the drug is authorized for marketing. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from our product and/or to prescribe the use of melphalan independently, our sales opportunities in the EEA will be significantly impaired.

While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval.

In April 2011, we obtained the required certification from our European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Delcath chemosaturation system. In order to maintain the right to affix the CE Mark in the EEA, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we will be subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Delcath chemosaturation system may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that the Delcath chemosaturation system is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for the Delcath chemosaturation system may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system by the FDA for use in the United States.

We cannot sell or market the Delcath chemosaturation system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Delcath chemosaturation system. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system. We are seeking approval of the Delcath chemosaturation system for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for the Delcath chemosaturation system with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of the Delcath chemosaturation system with melphalan or any other chemotherapeutic agent or compound we use in our system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our

inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company and our results of operations will be harmed.

In December 2010, we submitted our Section 505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. An NDA submitted under Section 505(b)(2) of the FFDCA permits the application to incorporate information required for approval from studies not conducted by or for the application and for which the applicant has not obtained a right of reference. Our Section 505(b)(2) application cited the safety information for melphalan submitted by prior NDA applicants for this drug. In February 2011, we received an RTF from the FDA for the NDA. In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. We have had subsequent communications with the FDA, including a meeting in early April to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011 which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. If we are unable to properly address the issues raised in the RTF to the FDA's satisfaction, we may be unable to resubmit our NDA to the FDA. Further, if we resubmit the NDA and subsequently receive a second RTF from the FDA, or, if it is accepted for filing and the FDA fails to approve the application after a substantive review, we will not be able to commercialize the Delcath chemosaturation system in the United States and our value and our results of operations will be harmed.

Even if we obtain regulatory approval for the Delcath chemosaturation system in the United States, our ability to market the Delcath chemosaturation system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. In the United States, we intend to seek approval for use of the Delcath chemosaturation system with melphalan in the treatment of ocular and cutaneous melanoma that has metastasized to the liver. If the FDA approves this application, our ability to market and promote the Delcath chemosaturation system would be limited to this indication for use only with melphalan in treating that specific disease, so even with FDA approval, the Delcath chemosaturation system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indication and we could be subject to enforcement action for off-label marketing.

Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If we do not obtain required approvals in the United States and in the countries outside of the EEA in which we aim to market the Delcath chemosaturation system, we may not be able to export or sell the Delcath chemosaturation system in those markets, which will limit our sales opportunities.

We intend to leverage our CE Mark to obtain required regulatory approvals for the Delcath chemosaturation system in other parts of the world, including Asia. However, our lack of experience conducting clinical trials outside the United States may negatively impact the approval process in foreign countries where we intend to seek approval for the Delcath chemosaturation system. We have not previously conducted multi-national clinical trials, and, particularly in countries where melphalan has not yet been approved, obtaining approval for the Delcath chemosaturation system may be challenging.

If we are unable to obtain and maintain required approval from one or more foreign countries outside of the EEA where we would like to sell the Delcath chemosaturation system, we will be unable to market our product as intended, our international market opportunity will be limited and the value of our company and our results of operations will be harmed.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the Delcath chemosaturation system for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase III clinical trial of the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and recently completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic melanoma stratified into four arms. We currently have no clinical trials on any other major forms of liver cancer.

We intend to conduct clinical trials for other indications, and it may take several years to complete the testing of the Delcath chemosaturation system with melphalan, other chemotherapeutic agents or other compounds for use in the treatment of the indications we wish to obtain approval of, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA may request additional clinical trials, including an additional Phase III trial, relating to our NDA submissions;
- the FDA may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause us to cease the development of the Delcath chemosaturation system for other indications. If we are unable to develop the Delcath chemosaturation system for other indications the future growth of our business could be negatively impacted.

While we have received approval of our clinical trial protocol from the FDA under a SPA, our failure to execute the clinical trial according to the agreed upon trial protocol may result in loss of FDA approval and invalidation of our clinical trials.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the design, execution, and analysis under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Pursuant to the FDA's guidance on SPAs, a SPA is documented in a SPA letter and/or the minutes of a Type A meeting. We conducted our Phase III trial under a SPA. The SPA may be invalidated for a number of reasons including our failure to execute the clinical trial according to the agreed upon trial protocol. While we believe our SPA is currently valid, our failure to execute the clinical trial according to the agreed upon trial procedures, or the FDA's identification of a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins, may lead to the invalidation of the SPA, and as a result, the trial itself may not be sufficient to serve as the primary basis of an effectiveness claim.

We rely on third parties to conduct certain of the clinical trials for the Delcath chemosaturation system, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for the Delcath chemosaturation system, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. In particular, we relied on a third party to conduct monitoring of our Phase II and Phase III clinical trials and collect the data for our planned resubmission of an NDA. We intend to rely upon third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements, and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and we may fail to obtain regulatory approval for the Delcath chemosaturation system if these requirements are not met.

Purchasers of the Delcath chemosaturation system in the EEA may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, we may not be able to successfully commercialize the Delcath chemosaturation system in the EEA.

We have obtained the right to affix the CE Mark for the Delcath chemosaturation system, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell the Delcath chemosaturation system. Until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that we will qualify for such funding. Even if we do qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of members states of the EEA will reimburse the product's use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath chemosaturation

system if they do not receive substantial reimbursement for the cost of using our product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

As the Delcath chemosaturation system is not currently approved by the FDA or other regulatory bodies outside the EEA, third-party payors in the United States and elsewhere will not reimburse the use of our product. Even if approval is obtained, inadequate reimbursement may harm results of operations.

The Delcath chemosaturation system is currently not approved by the FDA or any other regulatory body outside the EEA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the Delcath chemosaturation system's use since the product is currently not approved outside the EEA. We will seek reimbursement by third-party payors of the cost of the Delcath chemosaturation system after its use is approved, but there are no assurances that third-party payors in the United States or other countries will agree to cover the cost of procedures using the Delcath chemosaturation system at all or at rates that are adequate to cover the actual costs. Further, third-party payors may deny reimbursement if they determine that the Delcath chemosaturation system is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase the Delcath chemosaturation system, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the Delcath Chemosaturation System

There is only one approved third-party manufacturer of melphalan in the EEA. If this manufacturer fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EEA.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system is approved for marketing as a device only, and doctors will separately obtain melphalan for use with the Delcath chemosaturation system. Although melphalan has been approved in the EEA for over a decade, we are aware that there is currently only one approved manufacturer of melphalan in the EEA, with whom we have no supply arrangements or other affiliation, and therefore we will not have any control over the quality, availability, price or labeling of melphalan in that market. As a result, there may not be sufficient supply of melphalan for use with our system, and any adverse change in the sole manufacturer's commercial operations or regulatory approval status may seriously impair our sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where we intend to market the Delcath chemosaturation system. If supply of melphalan remains limited or unavailable, we will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

We purchase components for the Delcath chemosaturation system from third parties, some of which are sole-source suppliers.

The components of the Delcath system, including catheters, filters, introducers and chemotherapy agents, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet cGMP and quality systems requirements. Some states also have similar regulations. Many of the components of the Delcath chemosaturation system are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If Delcath or any of our suppliers fails to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials, and, once a product is approved for marketing, the manufacture, assembly or distribution thereof. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for the Delcath chemosaturation system, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply the Delcath chemosaturation system to the market.

All of the manufacturers of the components for the Delcath chemosaturation system must comply with a number of FDA and International Organization for Standardization, or ISO, and foreign regulatory agency requirements and regulations. If we or one of our suppliers fails to meet such requirements, we may need to change suppliers. If we are unable to successfully change suppliers, the successful completion of some of our future clinical trials and/or commercialization of the Delcath chemosaturation system could be jeopardized.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize the Delcath system in the United States.

We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC, or Synerx, and Bioniche Teoranta, or Bioniche, an affiliate of Mylan, Inc., for the supply of our branded melphalan for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. We intend to pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for the commercialization of the Delcath chemosaturation system, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we would first have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture the Delcath chemosaturation system, our ability to develop and commercialize the system would be impaired.

We will manufacture the Delcath chemosaturation system for distribution in the EEA in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver the Delcath chemosaturation system to purchasers.

In addition to limiting sales opportunities, delays in manufacturing the Delcath chemosaturation system may adversely affect our ability to obtain regulatory approval in other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture the Delcath chemosaturation system in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble the Delcath chemosaturation system in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

We do not have written contracts with all of our suppliers for the manufacture of components for the Delcath chemosaturation system.

We do not have written contracts with all our suppliers for the manufacture of components for the Delcath chemosaturation system. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of the Delcath chemosaturation system in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of the Delcath chemosaturation system are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of the Delcath chemosaturation system may be delayed.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing the Delcath chemosaturation system in the EEA.

We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath chemosaturation system. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors. However, we have not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though we have obtained the right to affix the CE Mark, we currently have no sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize the Delcath chemosaturation system in the EEA, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If we cannot successfully develop the infrastructure to market and commercialize the Delcath chemosaturation system, our ability to generate revenues in the EEA may be harmed, and we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

Competition for sales and marketing personnel is intense, and we may not be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect our business, financial condition and results of operations. Further, since our marketing strategy in the EEA includes establishing a network of third-party distributors, we must enter into collaborative arrangements with these third-party distributors. We may not be able to enter into such arrangements on reasonable terms or at all.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing the Delcath chemosaturation system in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.

Outside the EEA, even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize the Delcath chemosaturation system may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. In the United States, we intend to develop and train our own sales force to market our products, and in foreign countries other than in the EEA, we intend to market our products primarily through strategic partners and distributors. If we are unable to develop this infrastructure in the United States or to collaborate with an alliance partner to market our products in foreign countries, particularly in Asia, our efforts to commercialize the Delcath chemosaturation system or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing the Delcath chemosaturation system in the EEA, we may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so our EEA strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market the Delcath chemosaturation system in each of our target markets may fail in any or all of those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell the Delcath chemosaturation system may not be successful.

We have entered into a collaborative agreement with Chi Fu Trading Company for the country of Taiwan and intend to enter into one or more strategic alliances to further address markets outside the United States, particularly in Asia, and to help fund the development of additional indications or for use with additional chemotherapy agents within the United States. We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in our search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all.

Our collaborative relationships may never result in the successful development or commercialization of the Delcath chemosaturation system or any other product. The success of any collaboration will depend upon our ability to

perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with the Delcath chemosaturation system or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market the Delcath chemosaturation system in the EEA and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of our products to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to fulfill foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If we fail to overcome the challenges we encounter in our international operations, our business and results of operations may be materially adversely affected.

The Delcath chemosaturation system has never been used in a clinical setting in the EEA, so market acceptance of our product will depend on EEA healthcare professionals' efforts to learn about our product.

Since all of our prior clinical studies were conducted in the United States and the Delcath chemosaturation system has never been used in a clinical setting in the EEA, physicians in the EEA have no clinical experience with our product. As a result, the Delcath chemosaturation system may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors in the EEA until healthcare professionals are properly educated about the procedure. Market acceptance of the Delcath chemosaturation system in the EEA will depend upon a variety of factors including:

- whether our future clinical trials demonstrate significantly improved patient outcomes;
- our ability to educate and train physicians to perform the procedure and drive acceptance of the use of the Delcath chemosaturation system;

- our ability to convince healthcare payors that use of the Delcath chemosaturation system results in reduced treatment costs and improved outcomes for patients;
- whether the Delcath chemosaturation system replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology's value has been demonstrated.

We intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in the EEA, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop. Without effort from healthcare professionals to become educated about our product, the market may not accept the Delcath chemosaturation system and our efforts to commercialize the Delcath chemosaturation system in the EEA may be unsuccessful.

Similar considerations apply in any other market where we receive approval. Successful commercialization of the Delcath chemosaturation system in these markets will depend on market acceptance by healthcare professionals.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. The Delcath chemosaturation system competes with all forms of liver cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

The loss of key personnel could adversely affect our business.

The loss of a member of our senior executive staff could delay our obtaining FDA approval, our introducing the Delcath chemosaturation system commercially and our generating revenues and profits. Competition for experienced personnel is intense. If we cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

Risks Related to Patents, Trade Secrets and Proprietary Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and commercialize the Delcath chemosaturation system prior to the expiration of our patent protection.

Our patent portfolio consists of seven U.S. patents, one pending Patent Cooperation Treaty application, 22 issued foreign counterpart patents and four pending foreign counterpart patent applications. Certain of our U.S., European and other foreign patents have already expired and other U.S. patents relating to the Delcath chemosaturation system will expire beginning in 2012 through 2016.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath chemosaturation system or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our U.S. patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions.

Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Since we rely solely on trade secret protection in the EEA, our inability to maintain this trade secret protection will significantly limit our ability to commercialize the Delcath chemosaturation system in the EEA.

We presently only have valid issued patents for the current version of the Delcath chemosaturation system in the United States. Without patent protection in the EEA, the Delcath chemosaturation system will only be covered by trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge or that we will have adequate remedies for any such breach.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to the Delcath chemosaturation system will significantly impair our ability to commercialize the Delcath chemosaturation system in the EEA, and our value and results of operations will be harmed.

Similar considerations apply in any other foreign country where we receive approval. Since we do not have valid issued patents for the current version of the Delcath chemosaturation system in these countries, our ability to successfully commercialize the Delcath chemosaturation system will depend on our ability to maintain trade secret protection in these markets.

Risks Related to Products Liability

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that may arise from the testing, manufacture, marketing, sale and use of the Delcath chemosaturation system. In addition, because the Delcath chemosaturation system is intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the use of our system, the patient may be injured through the use of our system, which may subject us to claims. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Our Common Stock

Our stock price and trading volume may be volatile, which could result in unpredictable pricing of our equity securities.

The equity markets may experience periods of volatility, which could result in highly variable and unpredictable pricing of equity securities. The market price of our common stock could change in ways that may or may not be related to our business, our industry or our operating performance and financial condition. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- results of our clinical trials;
- regulatory delays, non-acceptance or non-approval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the Delcath chemosaturation system;
- product recalls;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;
- a challenge to one of our patents, either in court or via administrative proceedings in the United States Patent and Trademark Office;
- conditions generally affecting the healthcare and cancer treatment industries;
- the success of our operating strategy;
- our ability to repay our debt;
- future sales of equity or equity-related securities; and
- general financial, economic, domestic, international and other market conditions.

Many of these factors are beyond our control, and we cannot predict their potential impact on the price of our common stock. We cannot assure you that the market price of our common stock will not fluctuate or decline significantly in the future.

Our insiders beneficially own a significant portion of our stock.

As of April 15, 2011, our executive officers, directors and affiliated persons beneficially owned approximately 7.5% of our common stock. As a result, our executive officers, directors and affiliated persons will have significant influence to:

- elect or defeat the election of our directors;
- amend or prevent amendment of our certificate of incorporation or by-laws;
- effect or prevent a merger, sale of assets or other corporate transaction; and
- affect the outcome of any other matter submitted to the stockholders for vote.

Sales of significant amounts of shares held by our directors and executive officers, or the prospect of these sales, could adversely affect the market price of our common stock.

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.

The warrants issued in our September 2007 and June 2009 private placements contain anti-dilution provisions. The September 2007 warrants are subject to "full ratchet" protection upon certain equity issuances below $3.44 per share (as may be further adjusted). The June 2009 warrants are subject to an exercise price adjustment upon certain equity issuances below $3.60 per share (as may be further adjusted). In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

Anti-takeover provisions in our Certificate of Incorporation and By-laws and under our stockholder rights agreement may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.

Certain provisions of our Certificate of Incorporation and By-laws and of our stockholders rights agreement could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of our stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We also have a stockholder rights agreement that could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

Our common stock is listed on The NASDAQ Capital Market.

If we fail to meet the requirements of The NASDAQ Capital Market for continued listing, our common stock could be delisted. To keep such listing, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million. We are presently in compliance with these requirements.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ's corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of March 31, 2011, we had an aggregate of 26,843,323 shares of common stock authorized but unissued. Subject to certain volume limitations imposed by The NASDAQ Capital Market, we may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic acquisitions of other companies and assets, and we may issue shares of common stock in connection with those acquisitions or otherwise. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

Risks Related to This Offering

Our management team will have broad discretion over the use of the net proceeds from this offering.

Our management will use its discretion to direct the net proceeds from this offering. We intend to use the net proceeds from the sale of the shares for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. Our management's judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

Investors in this offering will experience immediate and substantial dilution.

The public offering price of the securities offered pursuant to this prospectus supplement is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. If the holders of outstanding options exercise those options at prices below the public offering price, you will incur further dilution.