DELCATH SYSTEMS INC
Form 10-Q
May 05, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2011.

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

For the transition period from _____ to _____

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	06-1245881
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

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

Yes ¨ No ¨

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

Large accelerated filer ¨ Accelerated filer x

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

As of May 5, 2011, 43,156,677 shares of the Company's common stock, $0.01 par value were outstanding.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

DELCATH SYSTEMS, INC.

Index

DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:

FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Index to Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Balance Sheets
(Unaudited)

	March 31, 2011	December 31, 2010
Assets:		
Current assets		
Cash and cash equivalents	$39,284,758	$45,621,453
Investments – Certificates of deposit	-	1,492,000
Prepaid expenses and other assets	1,286,488	1,784,276
Total current assets	40,571,246	48,897,729
Property, plant and equipment		
Furniture and fixtures	$1,615,718	$669,296
Computers and equipment	802,174	548,586
Leasehold improvements	988,256	939,518
	3,406,148	2,157,400
Less: accumulated depreciation	(693,741)	(477,420)
Property, plant and equipment, net	2,712,407	1,679,980
Total assets	43,283,653	50,577,709
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable and accrued expenses	$2,283,883	$3,192,310
Warrant liability	12,039,357	18,005,014
Total current liabilities	14,323,240	21,197,324
Deferred revenue	300,000	300,000
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.01 par value; 70,000,000 shares authorized; 43,156,677 and 43,028,146 shares issued and 42,977,787 and 42,932,460 outstanding at March 31, 2011 and December 31, 2010, respectively	431,567	430,281
Additional paid-in capital	146,217,572	144,782,807
Deficit accumulated during the development stage	(117,903,422)	(116,055,400)
Treasury stock, at cost; 28,100 shares at March 31, 2011 and December 31, 2010	(51,103)	(51,103)
Accumulated other comprehensive loss	(34,200)	(26,200)
Total stockholders' equity	28,660,414	29,080,385
Total liabilities and stockholders' equity	$43,283,654	$50,577,709

F-1

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statements of Operations and Comprehensive Income
(Unaudited)

	Three Months Ended March 31,		Cumulative from Inception (Aug 5, 1988) to March 31,
	2011	2010	2011
Costs and expenses:			
General and administrative expenses	$ 4,166,014	$ 2,546,172	$ 44,031,096
Research and development costs	3,648,224	2,941,110	60,238,388
Total costs and expenses	$ 7,814,238	$ 5,487,282	$ 104,269,484
Operating loss	(7,814,238)	(5,487,282)	(104,269,484)
Change in fair value of warrant liability (expense) income	5,965,657	(8,687,717)	(14,732,945)
Interest income	559	1,264	2,871,838
Other income	-	-	(102,753)
Interest expense	-	-	(171,473)
Net loss	(1,848,022)	(14,173,735)	(116,404,817)
Other comprehensive income (loss)	(8,000)	8,000	(34,200)
Total comprehensive loss	$ (1,856,022)	$ (14,165,735)	$ (116,439,017)
Common share data:			
Basic and diluted loss per share	$ (0.04)	$ (0.39)	
Weighted average number of shares of common stock outstanding	42,953,553	36,261,688	

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,		Cumulative from inception (Aug. 5, 1988) to March 31,
	2011	2010	2011
Cash flows from operating activities:			
Net loss	$(1,848,022)	$(14,173,735)	$(116,404,817)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	1,187,293	633,135	11,965,552
Restricted stock and warrant compensation expense	104,559	341,483	3,660,506
Depreciation expense	216,321	60,596	748,355
Amortization of organization costs	-	-	42,165
Loss on disposal of furniture and fixtures	-	-	10,172
Warrant liability fair value adjustment	(5,965,657)	8,687,717	14,732,945
Non-cash interest income	-	(1,151)	(11,375)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other assets	489,788	(349,208)	(1,270,657)
Increase (decrease) in accounts payable and accrued expenses	(908,427)	(575,461)	2,283,883
Deferred revenue	-	300,000	300,000
Net cash used in operating activities	$(6,724,145)	$(5,076,624)	$(83,943,631)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$(1,248,748)	$(447,261)	$(3,471,135)
Proceeds from sale of equipment	-	-	200
Purchase of short-term investments	-	(3,235,000)	(44,646,452)
Purchase of marketable equity securities	-	-	(46,200)
Proceeds from maturities of short-term investments	1,492,000	-	44,654,356
Organization costs	-	-	(42,165)
Net cash provided by (used in) investing activities	$243,252	$(3,682,261)	$(3,551,369)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$144,198	$206,159	$125,625,459
Repurchases of common stock	-	-	(51,103)
Dividends paid on preferred stock	-	-	(499,535)
Proceeds from short-term borrowings	-	-	1,704,964
Net cash provided by financing activities	$144,198	$206,159	$126,779,785
(Decrease) increase in cash and cash equivalents	(6,336,695)	(8,552,726)	39,284,758
Cash and cash equivalents at beginning of period	45,621,453	35,486,319	-
Cash and cash equivalents at end of period	$39,284,758	$26,933,593	$39,284,758
Supplemental cash flow information:			
Cash paid for interest	-	-	171,473
Supplemental non-cash activities:			
Cashless exercise of stock options	$-	$184,000	$1,244,594

Fair value of warrants issued	-	-	6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$-	$-	$9,153,567

Notes to Condensed Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Since its inception, the Company has directed its research efforts towards the development and clinical study of the Delcath chemosaturation system.

The Company's initial focus is on cancers in the liver. Currently, the Delcath chemosaturation system is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver while limiting the systemic exposure of this agent. The Company believes that the Delcath chemosaturation system is a platform technology that 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.

Note 2: Basis of Financial Statement Presentation

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The unaudited interim condensed financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company's results of operations, financial position and cash flows for the interim periods ended March 31, 2011 and 2010, and cumulative from inception (August 5, 1988) to March 31, 2011.

The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2010, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010 as filed with the Securities and Exchange Commission (the "SEC") on March 8, 2011 (the "2010 Form 10-K").

Research and Development Costs
Research and development costs include the costs of materials, personnel, outside services and applicable indirect costs incurred in development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

General and Administrative Costs
General and administrative costs include salaries and related expenses for the Company's executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Investments
Management determines the appropriate classification of securities at the time of purchase and reevaluates such classification as of each balance sheet date. The Company's securities are classified as either available-for-sale or held-to-maturity. Investments classified as held-to-maturity are stated at amortized cost. Investments classified as available-for-sale are stated at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity.

F-4

Deferred Revenue Recognition
Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. This agreement is discussed further in Note 6 to the Company's unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q.

Note 3: Recent Accounting Pronouncements

There were no recently issued accounting pronouncements that are expected to have a significant impact on financial reporting.

Note 4: Stock Option Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000, and 4,200,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Compensation and Stock Option Committee of the board of directors which determines the individuals to whom awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

During 2004 and 2009, respectively, the 2004 and 2009 Stock Incentive Plans became effective. Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the three month period ended March 31, 2011 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2010	3,760,650	$1.23-$15.54	$4.88	6.65
Granted	425,306	6.42-9.18	6.52	
Forfeited	-			
Exercised	(45,327)	2.44-3.28	3.18	
Outstanding at March 31, 2011	4,140,629	$1.23-$15.54	$5.07	6.83

For the three months ended March 31, 2011, the Company recognized compensation expense of approximately $1.1 million relating to options granted in previous years and $96,155 relating to options granted during 2011.

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

The Company accounts for stock-based compensation expense for non-employees using the fair-value method which requires the award to be re-measured at each reporting date until the award is vested. The

F-5

Company estimates the fair value using an option-pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

The assumptions used in the option-pricing model to determine the fair value of stock options awarded to employees are as follows:

	Three Months Ended March 31,	
	2011	2010
Dividend yield	None	None
Expected volatility	73.90% - 74.70%	73.10% – 75.04%
Weighted average volatility	74.26%	74.15%
Risk-free interest rates	2.29% - 2.54%	2.66% - 3.00%
Expected life (in years)	6.0	5.0 – 6.0

For the three months ended March 31, 2011, the Company recognized compensation expense of $77,357 relating to restricted stock granted in previous years. For the three months ended March 31, 2011, the Company recognized $27,202 relating to restricted stock granted during 2011.

Note 5: Assets and Liabilities Measured at Fair Value

Derivative warrant liability

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

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of the total proceeds to 2007 Warrants (see below). The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at $3.44 per share with 1,469,456 warrants outstanding at March 31, 2011. The shares were issued pursuant to an effective registration statement on Form S-3.

F-6

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants (see below), resulting in net proceeds of $476,255. The 2009 Warrants are currently exercisable at $3.60 per share with 1,043,478 warrants outstanding at March 31, 2011 and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

The $2.2 million in proceeds allocated to the 2009 Warrants and the $4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2011, the Company recorded pre-tax derivative instrument income of $5.97 million. The resulting derivative instrument liabilities totaled $12.0 million at March 31, 2011. Management expects that the Warrants will either be exercised or expire worthless, at which point the then existing derivative instrument liabilities will be credited to stockholders' equity. The fair value of the Warrants at March 31, 2011 was determined by using the Black-Scholes model assuming a risk free interest rate of 1.39% for the 2009 Warrants and 0.54% for the 2007 Warrants, volatility of 84.62% for the 2009 Warrants and 78.48% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

Management believes that the possibility of an actual cash settlement with a warrant holder is quite remote, and expects that the Warrants will either be exercised or expire worthless, at which point the then existing warrant liability will be credited to stockholders' equity when exercised or recorded through earnings if allowed to expire worthless.

Money Market Funds

Cash and cash equivalents includes a money market account valued at $39.3 million.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2011, aggregated by the level in the fair value hierarchy within which those measurements fall:

Assets and Liabilities Measured at Fair Value on a Recurring Basis at March 31, 2011

	Level 1	Level 2	Level 3	Balance at March 31, 2011
Assets				
Marketable equity securities	$ 12,000			$ 12,000
Money market funds	39,417,351			39,417,351
Total Assets	$ 39,429,351			$ 39,429,351
Liabilities				
Warrant liability			$ 12,039,357	$ 12,039,357
Total Liabilities			$ 12,039,357	$ 12,039,357

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Liability
Beginning balance	$18,005,014
Total decrease in the liability included in earnings	(5,965,657)
Ending balance	$12,039,357

Note 6: Research and Distribution Agreement

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

Pursuant to the Research and Distribution Agreement Chi-Fu will plan, fund and manage clinical studies of the Delcath system for chemosaturation therapy in the Field of Use with initial focus on the treatment of hepatic malignancies at not less than two and up to four sites in Taiwan, and will promptly file for TFDA approval of the Delcath system for chemosaturation therapy for as many indications of use as possible, promptly following Delcath's receipt of U.S. Food and Drug Administration ("FDA") approval of the Delcath system for chemosaturation therapy. Chi-Fu's exclusive right to market, sell and distribute the Delcath system for chemosaturation therapy in Taiwan in the Field of Use will begin on the date TFDA approval of the Delcath system for chemosaturation therapy is granted and will continue for the term of the Research and Distribution Agreement. Beginning on the first day of the month in which TFDA approval is obtained, Chi-Fu is obligated to purchase a minimum number of Delcath systems annually during the term of the Research and Distribution Agreement; with such minimum purchase requirements to increase annually over the remaining term of the Research and Distribution Agreement. The Research and Distribution Agreement requires Chi-Fu to pay Delcath $1 million in milestone payments, comprised of $300,000 paid upon execution of the Research and Distribution Agreement; $200,000 paid within thirty days of Delcath's receipt of a CE Mark for the Delcath system for chemosaturation therapy, and $500,000 within thirty days of Delcath's receipt of FDA approval for the Delcath system for chemosaturation therapy.

The term of the Research and Distribution Agreement commenced on February 9, 2010 and will continue for five (5) years from the first day of the month in which TFDA approval is obtained, following which the Research and Distribution Agreement will automatically renew for an additional five (5) years provided Chi-Fu has met all of its obligations under the Research and Distribution Agreement, including its minimum purchase requirements.

Note 7: Taxes

The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS") or any

F-8

states in connection with income taxes. The periods from December 31, 2004 to December 31, 2010 remain open to examination by the IRS and state authorities. Also note that for federal and state purposes, the tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

For the three months ended March 31, 2011, the Company recorded a state capital tax benefit of $62,500. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to $250,000 per year. Since this is not an income tax benefit, it is reflected as a component of general and administrative expenses.

Note 8: Subsequent Events

On April 13, 2011, the Company announced that it had been notified of CE Mark approval for it proprietary Hepatic CHEMOSAT™ Delivery System. The product has been approved with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark allows the Company to market and sell the product in countries in the European Economic Area.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim condensed financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the year ended December 31, 2010 (the "2010 Form 10-K") filed with the SEC to provide an understanding of our results of operations, financial condition and cash flows.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates" "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable termi often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Exchange Act"). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in the Company's 2010 Form 10-K in Item 1A under "Risk Factors" as well as in this report under "Risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture and commercialize the Delcath chemosaturation system; and
- our ability to successfully negotiate and enter into agreements with strategic and corporate partners.

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

Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Financial Statements of this report and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's 2010 Form 10-K.

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Since our inception, the Company has directed its research efforts towards the development and clinical study of the Delcath chemosaturation system.

Our initial focus is on cancers in the liver. Currently, the Delcath chemosaturation system is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver while limiting the systemic exposure of this agent. The Company believes 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.

In 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 and 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. The Phase III trial was conducted under a United States Food and Drug Administration, or FDA, Special Protocol Assessment ("SPA"). The Phase III and Phase II clinical trials were both subject to the terms and conditions of a Cooperative Research and Development Agreement, or CRADA, between us and the National Cancer Institute, or NCI. The FDA has informed us that the Delcath chemosaturation system with melphalan will be regulated as a drug. In Europe, the system will be regulated as a device.

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 chemosaturation system delivers high doses of anti-cancer agents (currently 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 Delcath chemosaturation system involves a series of three catheter insertions, each of which is made through standard interventional radiology techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs.

On April 13, 2011, the Company announced that it had been notified of CE Mark approval in Europe for it proprietary Hepatic CHEMOSAT™ Delivery System. The product has been approved with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark allows the Company to market and sell the product in countries in the European Economic Area (EEA).

We believe the Hepatic CHEMOSAT Delivery System may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in this region. We will now begin to build inventory and establish the commercialization infrastructure in Europe, including assembling a direct sales organization to initially cover countries in Northern Europe and establishing a network of third party distributors in Southern Europe. We will also begin establishing and training initial sites in select European countries as Centers of Clinical Excellence for the chemosaturation procedure.

In December 2010, the Company submitted its §505(b)(2) New Drug Application (NDA) to the FDA. 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. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

On February 22, 2011 the Company announced that it had received a Refusal to File letter from the FDA for its NDA. Delcath met with the FDA in early April to discuss the issues raised and to confirm our understanding of the remedies required for the resubmission of the filing. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by December 31, 2011. The Company will work closely with the FDA to fully understand the FDA's concerns and define a path forward for a successful resubmission of the application. Before the Company can market the Delcath chemosaturation system in the United States, it must obtain FDA approval of the drug and apparatus under a §505(b)(2) NDA.

On April 21, 2010, we announced that our Phase III clinical trial of the Delcath chemosaturation system with melphalan in patients with liver cancer had successfully met the study's primary endpoint of extended hepatic progression-free survival, or hPFS, in patients with melanoma metastases to the liver. These results were based on an independently corroborated intent-to-treat analysis. Patients in the Phase III clinical trial were randomized into one of two treatment arms, including immediate treatment with melphalan via the Delcath chemosaturation system or treatment with best alternative care. Comparing treatment with the Delcath chemosaturation system with melphalan to best alternative care, based on independent core lab review of patient scans, the statistical analysis revealed 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 to our Phase III ocular and cutaneous metastatic melanoma clinical trial, we recently concluded a separate multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer, stratified into four arms: neuroendocrine tumors (carcinoid and islet cell tumors), hepatocellular carcinoma (primary liver cancer), ocular or cutaneous melanoma (eye or skin cancer who have been previously treated with regional therapy using melphalan), and metastatic adenocarcinoma (glandular cancer).

Additional prospective clinical studies will likely be required to gain regulatory approval for other indications in the United States as well as in Asia. Generating this additional data is also expected to benefit our commercial sales activities in Europe. We intend to conduct a clinical trial of the Delcath system for chemosaturation therapy with melphalan for patients suffering from primary liver cancer. Our current intent is to conduct this trial in Asia and we plan to seek one or more corporate partners to help fund our efforts prior to commencing this study. 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 our chemosaturation system. As part of our development efforts, we intend to pursue United States pharmaceutical partners to co-develop and fund additional indications for the Delcath chemosaturation system.

We expect to market the Delcath chemosaturation system in Europe initially through a combination of direct sales representatives in Northern European countries and independent, third party distributors in Southern European countries. 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. 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. In the United States, our intention is to market the system ourselves focusing our initial marketing efforts on the over fifty 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 in these comprehensive cancer centers:

- 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.

Our expenses generally include costs for clinical studies, securing and maintaining patents and trademarks, regulatory activities, manufacturing and sourcing, personnel, rent for our facilities, and general corporate and working capital, including general and administrative expenses. Although we recently received our CE Mark, which allows us to sell our system in the EEA, we do not yet have a history of commercial sales. As such, we may continue to be dependent upon existing cash, the sale of equity or debt securities, or the establishment of strategic alliances with appropriate partners to fund future activities.

Since our inception we have raised approximately $125.1 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses over the remainder of 2011. Although we expect that the amount of capital required for operations, including preparation of the Company's submission to the FDA, operations at the manufacturing facility in upstate New York, and efforts to commercialize the

Delcath chemosaturation system in Europe, will continue to increase over the coming months, we believe that we have sufficient capital for operations through 2011.

Results of Operations

Three Months Ended March 31, 2011 and March 31, 2010

Delcath has operated at a loss for our entire history. The Company had a net loss for the three months ended March 31, 2011, of $1.8 million, which is a $12.3 million decrease in the net loss for the same period in 2010. The decrease in net loss is due to an increase of $2.3 million in total costs, which was offset by a $14.7 million change in the fair value of the warrant liability.

The Company's operating loss for the three months ended March 31, 2011 was $7.8 million, of which $1.3 million is non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans as discussed in more detail in Note 4 of the condensed financial statements included in this report. This compares to an operating loss for the three months ended March 31, 2010 of $5.5 million, of which $1.0 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

At the end of the first quarter of 2010, the Company had 24 full-time employees compared to 50 at the end of the first quarter of 2011. The increase in total costs can be primarily attributed to the Company's growth, which has led to an increase in payroll and overhead expenses, as well as non-cash stock and option expense. Additionally, the Company's continued expansion of research and development activities as well as preparations for commercialization have contributed to the rise in our total costs and expenses. We anticipate continued increases in our total costs and expenses throughout 2011.

General and administrative expenses increased by $1.6 million, from $2.5 million during the three months ended March 31, 2010 to $4.2 million for the three months ended March 31, 2011. The Company has continued its progress in transitioning from a development stage company focused solely on research and development activities to a commercial enterprise with staff dedicated to commercializing the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with these commercialization efforts. A significant portion of this increase is related to our increase in staffing and related overhead in order to expand our Marketing and Sales, Finance, and Manufacturing departments.

For the three months ended March 31, 2011, research and development expenses increased by approximately $700,000, from $2.9 million during the first quarter of 2010 to $3.6 million. During the first quarter of 2010, the Company was incurring expenses related to its Phase III clinical trial. The reduction in trial related expenses during the first quarter of 2011 was more than offset by an increase in expenses related to expanded research and development activities.

Interest income is from our money market account and certificates of deposit. During the three months ended March 31, 2011, the Company had interest income of $559, as compared to $1,264 for the same period in 2010.

Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and anticipates that losses will continue over the remainder of 2011. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing

arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments. The Company continues to move forward aggressively. As Delcath launches commercial sales and marketing activity in Europe and seeks FDA approval of the Delcath chemosaturation system in the United States we expect that both our expenses and capital expenditures will increase.

At March 31, 2011, we had cash and cash equivalents of $39.3 million, as compared to $45.6 million at March 31, 2010.

During the three months ended March 31, 2011, we used $6.7 million of cash in our operating activities, which compares to $5.1 million used in our operating activities during the comparable three month period in 2010. The increase of $1.6 million, or 32.5%, is primarily due to our preparations to commercialize the Delcath chemosaturation system, as well as an increase in compensation related expenses as the Company grew from 24 employees at March 31, 2010 to 50 employees at March 31, 2011. The Company expects that our cash allocated to operating activities will continue to increase as we aggressively move forward with our commercialization plans for Europe and incur regulatory expenses related to our NDA submission to the FDA. The Company believes it has sufficient capital to fund our operating activities through 2011.

At March 31, 2011, the Company's accumulated deficit was approximately $117.9 million. Because our business does not generate positive cash flow from operating activities, the Company may need to raise additional capital in order to fully commercialize our product or to fund development efforts relating to additional indications. Delcath believes that we will be able to raise additional capital in the event that we find it in our best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

In March 2010, the Company filed a registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings, up to $100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital from time to time. The registration statement became effective on April 13, 2010 (333-165677). The Company used this registration statement for its August 2010 public offering detailed in Note 3 to the Company's audited financial statements contained in the 2010 Form 10-K. Because the maximum aggregate offering price of all securities registered is $100,000,000, the Company's issuance of any securities will reduce the amount of other securities that it can issue pursuant to the registration statement on Form S-3.

The Company has funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2009 and 2010, along with our registered direct offerings in 2007 and 2009. As of December 31, 2010, Delcath had approximately $65,000,000 aggregate amount of common stock, preferred stock, stock purchase contracts, warrants and debt securities (or a combination of these securities) available to be issued under our effective registration statement on Form S-3. The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, capital expenditures and working capital. For a detailed discussion of our various sales of securities see Note 3 to the Company's audited financial statements contained in the 2010 Form 10-K.

Critical Accounting Estimates

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's financial statements contained in the 2010 Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the Delcath chemosaturation system as well as its research and development activities, the cost of which is required to be charged to

expense as incurred. This further limits our choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying FASB ASC 740 management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

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

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 5 to the Company's condensed financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under FASB ASC 820.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the value of its investments. However, the Company's marketable securities consist of short-term and/or variable rate instruments and, therefore, a change in interest rates would not have a material impact on the fair value of the Company's investment portfolio or related income.

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

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") in a subscription agreement with a single investor. The Company received gross proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.67 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants, resulting in net proceeds of $467,559. The 2009 Warrants are currently exercisable at $3.60 per share with 1,043,478 shares outstanding at March 31, 2011 and have a five-year term.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13.3 million in this transaction. The Company allocated $4.3 million of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at $3.44 per share with 1,469,456 warrants outstanding at March 31, 2011.

The $2.2 million in proceeds allocated to the 2009 Warrants and the $4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the three month period ended March 31, 2011, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of $5.97 million. The resulting derivative instrument liabilities totaled $12.0 million at March 31, 2011. The fair value of the Warrants at March 31, 2011 was determined by using an option pricing model assuming a risk free interest rate of 1.39% for the 2009 Warrants and 0.54% for the 2007 Warrants, volatility of 84.62% for the 2009 Warrants and 78.48% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of March 31, 2011 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

PART II:
OTHER INFORMATION

Item 1. Legal Proceedings

None.

8

Item 1A. Risk Factors

Our 2010 Form 10-K, in Part 1, Item 1A. "Risk Factors," contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition. There have been no material changes in these risk factors since such disclosure.

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

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 5. Other Information

Not Applicable.

Item 6. Exhibits

Exhibit No.		Description
31.1	**	Certification by Principal Executive Officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal Financial Officer Pursuant to Rule 13a 14.
32.1	***	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	***	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

** Filed herewith.

*** Furnished herewith.

SIGNATURES

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

May 5, 2011

DELCATH SYSTEMS, INC.
(Registrant)

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

Exhibit Index

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