DELCATH SYSTEMS INC
Form 10-Q
November 09, 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 September 30, 2011.

o 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 o

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 o No o

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	Accelerated filer x

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

As of August 7, 2011, 47,994,732 shares of the Company's common stock, $0.01 par value were outstanding.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Index to Financial Statements

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2011	December 31, 2010
Assets:		
Current assets		
Cash and cash equivalents	$ 40,962,993	$ 45,621,453
Investments – Certificates of deposit	3,735,000	1,492,000
Prepaid expenses and other assets	1,028,902	1,784,276
Total current assets	45,726,895	48,897,729
Property, plant and equipment		
Land	154,224	-
Furniture and fixtures	2,067,289	669,296
Computers and equipment	1,089,398	548,586
Leasehold improvements	1,121,366	939,518
	4,432,277	2,157,400
Less: accumulated depreciation	(1,200,798)	(477,420)
Property, plant and equipment, net	3,231,479	1,679,980
Total assets	$ 48,958,374	$ 50,577,709
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 657,929	$ 610,457
Accrued expenses	4,377,291	2,581,853
Warrant liability	3,140,996	18,005,014
Total current liabilities	8,176,216	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; 48,232,774 and 43,028,146 shares issued and 47,993,732 and 42,932,460 outstanding at September 30, 2011 and December 31, 2010, respectively	482,328	430,281
Additional paid-in capital	171,762,847	144,782,807
Deficit accumulated during the development stage	(131,671,714)	(116,055,400)
Treasury stock, at cost; 28,100 shares at September 30, 2011 and December 31, 2010	(51,103)	(51,103)
Accumulated other comprehensive loss	(40,200)	(26,200)
Total stockholders' equity	40,482,158	29,080,385
Total liabilities and stockholders' equity	$ 48,958,374	$ 50,577,709

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Consolidated Statements of Operations and Comprehensive Income
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative from Inception (Aug 5, 1988) to September 30,
	2011	2010	2011	2010	2011
Costs and expenses:					
General and administrative expenses	$5,744,142	$3,165,414	$15,148,228	$9,413,709	$55,013,310
Research and development costs	6,437,186	4,256,048	15,333,306	11,800,267	71,923,470
Total costs and expenses	12,181,328	7,421,462	30,481,534	21,213,976	126,936,780
Operating loss	(12,181,328)	(7,421,462)	(30,481,534)	(21,213,976)	(126,936,780)
Change in fair value of warrant liability, net	3,871,727	(2,111,543)	14,864,018	(10,164,567)	(5,834,584)
Interest income	537	2,949	1,202	6,824	2,872,481
Other income and interest expense	-	-	-	-	(274,226)
Net loss	(8,309,064)	(9,530,056)	(15,616,314)	(31,371,719)	(130,173,109)
Other comprehensive income (loss)	(3,000)	(3,000)	(14,000)	(4,000)	(40,200)
Total comprehensive loss	$(8,312,064)	$(9,533,056)	$(15,630,314)	$(31,375,719)	$(130,213,309)
Common share data:					
Basic and diluted loss per share	$(0.18)	$(0.24)	$(0.35)	$(0.83)	
Weighted average number of shares of common stock outstanding, basic and diluted	46,961,123	39,712,207	44,315,838	37,703,577	

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,		Cumulative from inception (Aug. 5, 1988) to September 30,
	2011	2010	2011
Cash flows from operating activities:			
Net loss	$ (15,616,314)	$ (31,371,719)	$ (130,173,109)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	2,920,648	2,667,275	13,698,907
Restricted stock and warrant compensation expense	437,503	1,272,047	3,993,450
Depreciation expense	723,379	318,886	1,255,413
Amortization of organization costs	-	-	42,165
Loss on disposal of furniture and fixtures	-	6,730	10,172
Warrant liability fair value adjustment	(14,864,018)	10,164,567	5,834,584
Non-cash interest income	(533)	(4,467)	(12,268)
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other assets	741,907	(211,149)	(1,018,538)
Increase (decrease) in accounts payable and accrued expenses	1,842,910	(42,186)	5,035,220
Deferred revenue	-	300,000	300,000
Net cash used in operating activities	(23,814,518)	(16,900,016)	(101,034,004)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(2,274,877)	(1,341,930)	(4,497,264)
Proceeds from sale of equipment	-	-	200
Purchase of short-term investments	(3,735,000)	(3,235,000)	(48,381,452)
Purchase of marketable equity securities	-	-	(46,200)
Proceeds from maturities of short-term investments	1,492,000	747,000	44,654,356
Organization costs	-	-	(42,165)
Net cash used in investing activities	(4,517,877)	(3,829,930)	(8,312,525)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	23,673,935	37,008,746	149,155,196
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	23,673,935	37,008,746	150,309,522
(Decrease) increase in cash and cash equivalents	(4,658,460)	(16,278,800)	40,962,993
Cash and cash equivalents at beginning of period	45,621,453	35,486,319	-
Cash and cash equivalents at end of period	$ 40,962,993	$ 51,765,119	$ 40,962,993
Supplemental cash flow information:			

Cash paid for interest	$ -	$ -	$ 171,473
Supplemental non-cash activities:			
Cashless exercise of stock options and shares withheld upon restricted stock vesting	$ (61,031)	$ 424,332	$ 1,183,563
Fair value of warrants issued	$ -	$ -	$ 6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$ -	$ 8,541,937	$ 9,153,567

See accompanying notes to condensed consolidated financial statements.

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Notes to Condensed Consolidated Financial Statements

Note 1: Description of Business

Delcath Systems, Inc. is a development stage specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath concluded a Phase III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Hepatic CHEMOSAT delivery system in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States.

Note 2: Consolidated Financial Statements

The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2011 and 2010 and Cumulative from Inception (August 5, 1988) to September 30, 2011 include the accounts of Delcath Systems, Inc. and its wholly owned subsidiary, Delcath Systems Limited (collectively, the “Company”).

Note 3: Basis of Financial Statement Presentation

The accompanying condensed consolidated 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. The preparation of financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, income taxes and research and development costs. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The unaudited interim condensed consolidated 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 September 30, 2011 and 2010, and cumulative from inception (August 5, 1988) to September 30, 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”).

Summary of Significant Accounting Policies

The Company describes its significant accounting policies in Note 1 to the Company’s Financial Statements contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There were no significant changes in the Company’s accounting policies since the end of fiscal 2010.

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.

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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. The Company will amortize deferred revenue over the expected obligation period of the agreement once this amount is reasonably determinable.

Note 4: Recent Accounting Pronouncements
In June 2011, the FASB issued authoritative guidance aimed at increasing the prominence of items reported in other comprehensive income in the financial statements. This guidance requires companies to present comprehensive income in a single statement below net income or in a separate statement of comprehensive income immediately following the income statement. Companies will no longer be allowed to present comprehensive income on the statement of changes in shareholders' equity. In both options, companies must present the components of net income, total net income, the components of other comprehensive income, total other comprehensive income and total comprehensive income. This guidance will become effective for fiscal years and interim periods beginning after December 15, 2011 and will require retrospective application for all periods presented. The adoption of this guidance may impact the presentation of the company’s condensed consolidated financial statements, but it will not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income.

In May 2011, the FASB provided amendments to achieve a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. The amendments change certain fair value measurement principles and enhance the disclosure requirements particularly for Level 3 fair value measurements. These amendments will be effective prospectively for interim and annual periods beginning after December 15, 2011. The Company is currently evaluating the impact of adopting these amendments, but currently believes there will be no significant impact on its condensed consolidated financial statements.

Note 5: Stock Incentive 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.

Stock Options
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 nine month period ended September 30, 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	648,591	3.46 – 9.18	6.52	
Forfeited	(136,900)	1.40 - 9.93	4.65	
Exercised	(45,327)	2.44 – 3.28	3.18	
Outstanding at September 30, 2011	4,227,014	$ 1.23 – $15.54	$ 5.05	6.42

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For the three and nine months ended September 30, 2011, the Company recognized stock option compensation expense of $403,350 and $2,210,535 respectively, relating to options granted in previous years and $308,951 and $710,113 respectively, relating to options granted during 2011, for a total of $712,301 and $2,920,648, respectively.

For the three and nine months ended September 30, 2010, the Company recognized stock option compensation expense of $1,124,590 and $2,667,275, respectively.

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 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:

	Nine Months Ended September 30,	
	2011	2010
Dividend yield	None	None
Expected volatility	73.88% – 79.11%	72.16% – 75.35%
Weighted average volatility	74.55%	73.62%
Risk-free interest rates	1.13% – 2.54%	1.45% – 3.11%
Expected life (in years)	5.0 – 6.0	5.0 – 6.0

Restricted Stock

For the three and nine months ended September 30, 2011, the Company recognized compensation expense of $19,863 and $133,033 respectively, relating to restricted stock granted in previous years. For the three and nine months ended September 30, 2011, the Company recognized $164,461 and $304,470 respectively, relating to restricted stock granted during 2011, for a total of $184,324 and $437,503, respectively.

For the three and nine months ended September 30, 2010, the Company recognized restricted stock compensation expense of $251,849 and $1,272,347, respectively.

Note 6: 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 the Company's 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 (FASB ASC 820-10-35-40). The riskless rate of return is a Level 2 input as defined in FASB ASC 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.

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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 September 30, 2011. The shares were issued pursuant to an effective registration statement on Form S-3.

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 September 30, 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 nine month period ended September 30, 2011, the Company recorded pre-tax derivative instrument income of $14.9 million. The resulting derivative instrument liabilities totaled $3.1 million at September 30, 2011, as compared to $18.0 million at December 31, 2010. The fair value of the Warrants at September 30, 2011 was determined by using the Black-Scholes model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.13% for the 2007 Warrants, volatility of 84.35% for the 2009 Warrants and 76.69% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 for the 2009 Warrants and September 2012 for the 2007 Warrants).

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 $39.4 million.

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The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 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 September 30, 2011

	Level 1	Level 2	Level 3	Balance at September 30, 2011
Assets				
Marketable equity securities	$ 6,000	$ -	$ -	$ 6,000
Money market funds	39,364,650	-	-	39,364,650
Total Assets	$ 39,370,650	$ -	$ -	$ 39,370,650
Liabilities				
Warrant liability	$ -	$ -	$ 3,140,996	$ 3,140,996
Total Liabilities	$ -	$ -	$ 3,140,996	$ 3,140,996

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Liability
Beginning balance	$ 18,005,014
Total decrease in the liability included in earnings	(14,864,018)
Ending balance	$ 3,140,996

Note 7: Net Loss

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options and warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at September 30, 2011 and 2010 upon exercise or conversion that were not included in the computation of net loss per share totaled 6,739,948 and 6,332,313 shares, respectively.

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Note 8: 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 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 nine months ended September 30, 2011, the Company recorded a state capital tax benefit of $187,500. 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 9: Subsequent Events

On October 26, 2011, Delcath Systems, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has responded to the Company's request made in September for a pre-New Drug Application (NDA) meeting and has scheduled a date in mid-January 2012.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim condensed consolidated 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 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 Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in this report under "risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the 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 Consolidated Financial Statements of this report and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K.

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology, initially cancers in the liver. Since our inception, the Company has directed its 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.

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Product Development

The Company is developing a second generation chemosaturation system featuring higher efficiency filtration cartridges. We believe the improved filter will help to further minimize a patient's systemic exposure to the chemotherapeutic agent, melphalan hydrochloride, and may offer the patient and the physician a variety of additional benefits including reduced patient recovery times, the ability to use concominant therapies and the expanded ability for additional beneficial treatments using the system. The second generation chemosaturation system contains several modified features intended to help improve the ease of use by a physician by providing the cartridges in an easy mount system. This second generation product is expected to receive CE Mark and be available for commercial distribution in Europe in 2012.

European Market Commercialization

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath chemosaturation system featuring the first generation filtration cartridges. The right to affix the CE Mark allows us to market and sell the Delcath chemosaturation system ("ChemoSAT") in the European Economic Area (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 entered into a long term lease to establish our European headquarters in Galway, Ireland and formed Delcath Systems, Limited, an Irish company under which we will establish European operations. We have initiated the renovation of our facility in Galway. We are actively recruiting for our European operations and have begun to hire key employees in specific countries in Europe. We plan to utilize third-party contract sales organizations and a direct sales force in the United Kingdom, Germany and the Netherlands and distributors in France, Italy and Spain. We are planning an initial launch and clinical training for the ChemoSAT system in select centers in Europe and, following the initial launch, intend to establish clinical training centers to educate and train physicians and healthcare payors in these countries in order to develop key opinion thought leadership and foster initial market acceptance.

Clinical Trials

The Company has completed a Phase III clinical trial using the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and a multi-arm Phase II clinical trial using the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer. Additionally, the Company plans to implement an Expanded Access Program (EAP) at several sites in the United States in early 2012.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the clinical trial protocol's design, execution, and analysis under a Special Protocol Assessment (SPA). A SPA is an evaluation by the U.S. Food and Drug Administration (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 (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 (hPFS) compared to the best alternative care (BAC). Our Phase III trial successfully met the study's primary endpoint of extended hPFS. We recently announced updated results which include data from patients through March 2011, an additional 12 months of data maturation from our initial announcement. With respect to the study's primary endpoint of hPFS, the updated investigator-assessed results showed that patients in the chemosaturation arm demonstrated median hPFS of 8.0 months compared to 1.6 months in the BAC arm, a significant 6.4 month extension of hPFS. Median overall PFS in the chemosaturation arm was 6.7 months compared to 1.6 months in the BAC arm, an increase of 5.1 months. An analysis of survival trends by patient cohorts indicated that patients treated with chemosaturation, including crossover patients, had a median survival of 11.4 months compared to 4.1 months for BAC patients who did not receive chemosaturation. As of June 30, 2011, 11 patients treated with chemosaturation were still alive compared to two patients in the BAC arm who did not receive chemosaturation.

In addition, we 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 II clinical trial included four patient cohorts: hepatobiliary cancers, and metastatic cancers of neuroendocrine, ocular or cutaneous melanoma, and colorectal (adenocarcinoma) origins.

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There were nine patients with tumors of hepatobiliary origin: five hepatocellular carcinomas (HCC) and four cholangiocarcinomas. HCC is the most common primary cancer of the liver, with approximately 500,000 new cases diagnosed worldwide annually. Both groups had positive efficacy signals. The responses were especially encouraging in the HCC cohort where all patients received confirmed partial response or durable stable disease.

In the Phase II trial's metastatic neuroendocrine (mNET) cohort, 24 patients with unresectable mNET in the liver underwent an average of three chemosaturation procedures. The primary endpoint of overall hepatic response rate (ORR) among the 20 evaluable patients was 70%, including one patient who presented with a confirmed complete response (CR) and 13 with confirmed partial responses (PR). Currently available treatment options for patients with unresectable neuroendocrine liver metastases have response rates around 5%. Four patients had stable disease (SD) and two progressed at their first evaluation, giving a tumor growth control rate of 90%. As for secondary endpoints, the median overall survival in all 24 patients (on an intent to treat or ITT basis) was reported as 30.4 months and the median hepatic progression-free survival (hPFS) was reported as 15.5 months.

In the Phase II trial’s metastatic colorectal (adenocarcinoma) cohort, sixteen patients with very late stage colorectal cancer liver metastases were recruited into this arm. No significant responses were noted among these patients as they had been heavily pre-treated with numerous chemotherapeutic and regional modalities that, along with anatomical and disease-related factors in a few, prevented sufficient melphalan exposure. The predominant accrual of very late stage patients reflects the changing referral and treatment patterns at the NCI at the time that this study was conducted, but it was not a design feature of the study. We recently conducted in vitro experiments evaluating colorectal tumor cell lines that were exposed to melphalan at concentrations achieved during chemosaturation, which showed encouraging signals of cell-death induction. This, combined with published reports of demonstrated efficacy with high dose melphalan delivered with surgical isolation perfusion, has convinced us to continue to study the efficacy of our chemosaturation system in this patient population that currently has few treatment options

The safety profiles of the chemosaturation system in all four cohorts of the Phase II clinical trial were consistent with the Company's Phase III melanoma trial.

Regulatory
United States
Based on our 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 (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. We continue our efforts to prepare our resubmission to the FDA, including data gathering and remonitoring, in order to address the issues raised in the RTF. The FDA recently responded to our request for a pre-NDA meeting and we are scheduled to have a meeting with the FDA to discuss our application in mid-January 2012.

Other Markets

Since receiving the CE Mark for the ChemoSAT system, we have been begun the process of seeking regulatory approval in several other countries where we can leverage our CE Mark. We recently completed the product notification process with the Medicines and Medical Device Safety Authority in New Zealand which allows us to sell the ChemoSAT system in New Zealand and we expect to begin supplying the system through an authorized distributor in 2012. We have also completed our regulatory filings with the Australian Therapeutic Goods Administration and Singapore Health Sciences. We intend to file and seek regulatory approval in other markets in Asia, including Hong Kong and Korea, as well as China and Japan where local clinical trials may be required, and in Latin America and the Middle East.

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Results of Operations

Since our inception we have raised approximately $149.2 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses over the year. We expect that the amount of capital required for operations including efforts to commercialize the Delcath chemosaturation system in Europe, preparation of the Company's submission to the FDA, and continued research and development activities will continue to increase for the foreseeable future.

Three Months Ended September 30, 2011 and September 30, 2010

Delcath has operated at a loss for our entire history. The Company had a net loss for the three months ended September 30, 2011, of $8.3 million, which is a $1.2 million decrease in the net loss for the same period in 2010. The decrease in net loss is due to a $6.0 million change in the fair value of the warrant liability, which was offset by an increase of $4.8 million in operating costs.

The Company's operating loss for the three months ended September 30, 2011 was $12.2 million, of which approximately $900,000 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 5 of this filing. This compares to an operating loss for the three months ended September 30, 2010 of $7.4 million, of which approximately $1.4 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

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. At the end of the third quarter of 2011 the Company had 74 full-time employees compared to 44 at the end of the third quarter of 2010. Additionally, the Company's preparations for commercialization in Europe, continued expansion of research and development (R&D) activities and regulatory expenses related to our submission to the FDA has contributed to the increase in our total costs and expenses. We anticipate continued increases in our total costs and expenses as the Company continues to aggressively move forward with our commercialization and R&D plans.

General and administrative expenses increased to $5.7 million for the three months ended September 30, 2011, from $3.2 million for the three months ended September 30, 2010. The Company is continuing its progress in transitioning from a development stage company 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 our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to $6.4 million for the three months ended September 30, 2011, from $4.3 million during the three months ended September 30, 2010. The increase in expenses is primarily related to our expanded research and development activities and regulatory expenses related to our submission to the FDA.

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Interest income is generated from our money market account and certificates of deposit. During the three months ended September 30, 2011, the Company had interest income of $537, as compared to $2,949 for the same period in 2010. For the three months ended September 30, 2010, the Company earned interest from certificates of deposit which matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the three months ended September 30, 2011.

Nine Months Ended September 30, 2011 and September 30, 2010
The Company had a net loss for the nine months ended September 30, 2011, of $15.6 million, which is a $16.2 million decrease in the net loss for the same period in 2010. The decrease in net loss is primarily due to a $25.5 million change in the fair value of the warrant liability, which was offset by an increase of approximately $9.3 million in total costs.

The Company's operating loss for the nine months ended September 30, 2011 was $30.5 million, of which approximately $3.4 million is non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans as discussed in more detail in Note 5 of this filing. This compares to an operating loss for the nine months ended September 30, 2010 of $21.2 million, of which approximately $3.9 million was non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans.

General and administrative expenses increased to $15.1 million for the nine months ended September 30, 2011 from $9.4 million for the nine months ended September 30, 2010. The Company is continuing its progress in transitioning from a development stage company 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 our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to $15.3 million for the nine months ended September 30, 2011, from $11.8 million during the first nine months of 2010. Our continued hiring has also contributed to an increase in research and development expenses. During 2010, the Company was incurring expenses related to wrapping up its Phase III clinical trial. The reduction in trial related expenses during 2011 was more than offset by an increase in expenses related to our expanded research and development activities and regulatory expenses related to our submission to the FDA.

Interest income is generated from our money market account and certificates of deposit. During the nine months ended September 30, 2011, the Company had interest income of $1,202, as compared to $6,824 for the same period in 2010. For the nine months ended September 30, 2010, the Company earned interest from certificates of deposit which matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the nine months ended September 30, 2011.

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 coming years. 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 regulatory 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 commences commercial sales and marketing activity in Europe and seeks FDA approval of the Delcath chemosaturation system in the U.S. we expect that both our expenses

and capital expenditures will increase.

At September 30, 2011, we had cash and cash equivalents of $41.0 million, as compared to $51.8 million at September 30, 2010. Cash and cash equivalents does not include $3.7 million invested in certificates of deposit at September 30, 2011 or $2.5 million invested in certificates of deposit at September 30, 2010. During the nine months ended September 30, 2011, we used $23.8 million of cash in our operating activities, which compares to $16.9 million used in our operating activities during the comparable nine month period in 2010. The increase of $6.9 million, or 40.9%, is primarily due to our preparations to commercialize the Delcath chemosaturation system, expenses related to our remonitoring efforts to prepare our submission to the FDA, as well as an increase in compensation related expenses as the Company grew from 44 employees at September 30, 2010 to 74 employees at September 30, 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 continue to incur regulatory expenses related to our submission to the FDA. The Company believes it has sufficient capital to fund our operating activities.

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At September 30, 2011, the Company's accumulated deficit was approximately $131.7 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. 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 at a later date. 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 Annual Report on Form 10-K. In July 2011, the Company completed the sale of 5,000,000 shares of its common stock pursuant to an underwriting agreement with Jefferies & Company, Inc., raising approximately $23.6 million after expenses. 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, 2010, and 2011 along with our registered direct offerings in 2007 and 2009. As of July 31, 2011, Delcath had approximately $39,750,000 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 Annual Report on 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 Annual Report on Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to 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.

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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 consolidated condensed financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under FASB ASC 820.

ItemQuantitative and Qualitative Disclosure about Market Risk
3.

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 September 30, 2011 and have a five-year term.

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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 September 30, 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 nine month period ended September 30, 2011, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of $14.9 million. The resulting derivative instrument liabilities totaled $3.1 million at September 30, 2011. The fair value of the Warrants at September 30, 2011 was determined by using an option pricing model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.13% for the 2007 Warrants, volatility of 84.35% for the 2009 Warrants and 76.69% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

ItemControls and Procedures
4.

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 September 30, 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.

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PART II:
OTHER INFORMATION

ItemLegal Proceedings
1.
None.

ItemRisk Factors
1A.
None.

ItemUnregistered Sales of Equity Securities and Use of Proceeds
2.
Not Applicable.

ItemDefaults upon Senior Securities
3.
Not Applicable.

ItemOther Information
5.
Not Applicable.

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ItemExhibits
6.

Exhibit No.		Description
10.1	**	Lease Agreement, dated August 2, 2011
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 Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Extension Calculation Linkbase Document
101.LAB		XBRL Extension Label Linkbase Document
101.PRE		XBRL Extension Presentation Linkbase Document

** Filed herewith.

*** Furnished herewith.

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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.

November 9, 2011

DELCATH SYSTEMS, INC.
(Registrant)

/s/Graham G. Miao
Graham G. Miao
Chief Financial Officer
(Principal Financial Officer)

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101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Extension Calculation Linkbase Document
101.LAB		XBRL Extension Label Linkbase Document
101.PRE		XBRL Extension Presentation Linkbase Document

** Filed herewith.

*** Furnished herewith.