DELCATH SYSTEMS INC
Form 10-Q
November 02, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2010.

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

For the transition period from _____ to _____

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	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 filer o	Accelerated filer x
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 **, ** 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 Financial Statements (Unaudited)

Index to Financial Statements

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Balance Sheets
(Unaudited)

	September 30, 2010	December 31, 2009
Assets:		
Current assets		
Cash and cash equivalents	$ 51,765,119	$ 35,486,319
Investments – CDs	2,488,000	–
Prepaid expenses and other assets	1,011,033	799,416
Total current assets	55,264,152	36,285,735
Property, plant and equipment		
Furniture and fixtures	$ 529,051	$ 36,800
Computers and equipment	493,373	78,063
Leasehold improvements	839,212	431,425
	1,861,636	546,288
Less: accumulated depreciation	(324,016)	(24,982)
Property, plant and equipment, net	1,537,620	521,306
Total assets	$ 56,801,772	$ 36,807,041
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable and accrued expenses	$ 1,799,294	$ 1,841,480
Warrant liability	12,829,844	11,207,214
Total current liabilities	14,629,138	13,048,694
Deferred revenue	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; 42,893,163 and 36,223,097 shares issued and 42,865,063 and 36,194,997 outstanding at September 30, 2010 and December 31, 2009, respectively	428,932	362,231
Additional paid-in capital	142,258,478	92,835,174
Deficit accumulated during the development stage	(100,743,473)	(69,371,755)
Treasury stock, at cost; 28,100 shares at September 30, 2010 and December 31, 2009	(51,103)	(51,103)
Accumulated other comprehensive loss	(20,200)	(16,200)
Total stockholders' equity	41,872,634	23,758,347
Total liabilities and stockholders' equity	$ 56,801,772	$ 36,807,041

See accompanying notes to condensed financial statements.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed 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,
	2010	2009	2010	2009	2010
Costs and expenses:					
General and administrative expenses	$ 3,165,414	$ 1,430,990	$ 9,413,709	$ 2,152,331	$ 36,091,513
Research and development costs	4,256,048	2,327,167	11,800,267	5,983,392	50,834,733
Total costs and expenses	$ 7,421,462	$ 3,758,157	$ 21,213,976	$ 8,135,723	$ 86,926,246
Operating loss	(7,421,462)	(3,758,157)	(21,213,976)	(8,135,723)	(86,926,246)
Change in fair value of warrant liability, net	(2,111,543)	(3,830,801)	(10,164,567)	(8,296,958)	(14,911,801)
Interest income	2,949	3,054	6,824	71,982	2,867,405
Other income	-	-	-	1,689	(102,753)
Interest expense	-	-	-	-	(171,473)
Net loss	(9,530,056)	(7,585,904)	(31,371,719)	(16,359,010)	(99,244,868)
Other comprehensive income (loss)	(3,000)	(8,000)	(4,000)	6,000	(20,200)
Total comprehensive loss	$ (9,533,056)	$ (7,593,904)	$ (31,375,719)	$ (16,353,010)	$ (99,265,068)
Common share data:					
Basic and diluted loss per share	$ (0.24)	$ (0.29)	$ (0.83)	$ (0.64)	
Weighted average number of shares of common stock outstanding	39,712,207	26,337,717	37,703,577	25,753,795	

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,		Cumulative from inception (Aug. 5, 1988) to September 30,
	2010	2009	2010
Cash flows from operating activities:			
Net loss	$ (31,371,719)	$ (16,359,010)	$ (99,244,869)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	2,667,275	502,534	9,606,214
Stockcompensation expense	1,272,047	225,083	3,152,741
Depreciation expense	318,886	5,027	378,629
Loss on disposal of furniture and fixtures	6,730	-	10,172
Amortization of organization costs	-	-	42,165
Non-cash interest income	(4,467)	-	(12,371)
Warrant liability fair value adjustment	10,164,567	8,296,958	14,911,802
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other assets	(211,149)	(334,781)	(980,565)
Increase (decrease) in accounts payable and accrued expenses	(42,186)	68,622	1,799,294
Deferred revenue	300,000	-	300,000
Net cash used in operating activities	$ (16,900,016)	$ (7,595,567)	$ (70,036,788)
Cash flows from investing activities:			
Purchase of equipment or furniture and fixtures	$ (1,341,930)	$ (20,924)	$ (1,926,622)
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	747,000	4,048,614	42,166,356
Organization costs	-	-	(42,165)
Net cash (used in) provided by investing activities	$ (3,829,930)	$ 4,027,690	$ (4,494,883)
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	$ 37,008,746	$ 2,667,234	$ 125,142,464
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	$ 37,008,746	$ 2,667,234	$ 126,296,790
(Decrease) increase in cash and cash equivalents	16,278,800	(900,643)	51,765,119
Cash and cash equivalents at beginning of period	35,486,319	6,939,233	-
Cash and cash equivalents at end of period	$ 51,765,119	$ 6,038,590	$ 51,765,119
Supplemental cash flow information:			
Cash paid for interest	-	-	171,473
Supplemental non-cash activities:			
Cashless exercise of stock options	$ 424,332	$ -	$ 544,116

Fair value of warrants issued	$ -	$ 2,190,979	$ 6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	$ 8,541,937	$ -	$ 8,541,937

See accompanying notes to condensed financial statements.

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. 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 has not yet received FDA or any foreign regulatory approval for commercial sale of its system.

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 September 30, 2010 and 2009, and cumulative from inception (August 5, 1988) to September 30, 2010. In connection with the preparation of the condensed financial statements and in accordance with the recently issued Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 855-10, the Company evaluated subsequent events through the date of filing.

The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2009, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission (the "SEC") on February 26, 2010 (the "2009 Form 10-K").

Research and Development Costs

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

General and Administrative Costs

General and administrative costs include salaries and related expenses for our executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

Deferred Revenue Recognition

Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. This agreement is discussed further in Note 6 to the Company's

unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q. The Company will amortize deferred revenue over the expected obligation period of the agreement once this amount is reasonably determinable.

Investments

The Company invests the majority of its cash in money market funds and certificates of deposit. The money market funds are accounted for based on the guidance for fair value measurements and are discussed further in Note 5 to the Company's unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q. The Company's certificates of deposit are accounted for based on the guidance for investments, which requires securities to be categorized as either trading, available-for-sale or held-to-maturity. The certificates of deposit are classified as held-to-maturity and, as such, are carried at amortized cost.

The Company also holds shares of Aethlon Medical which are valued at $26,000 and are classified as an available for sale security in Prepaid expenses and other assets. The change in value is recorded in Accumulated other comprehensive loss on the Balance Sheet and is reflected in Other comprehensive income (loss) on the Condensed Statements of Operations and Comprehensive Income.

Note 3: Recent Accounting Pronouncements

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

Note 4: 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 nine month period ended September 30, 2010 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2009	3,345,000	$ 1.23 – $6.18	$ 3.72	6.58
Granted	600,400	5.28 – 15.54	9.79	
Forfeited	(75,000)	2.78 – 6.18	3.46	
Exercised	(140,000)	1.43 – 6.18	3.27	
Outstanding at September 30, 2010	3,730,400	$ 1.23 –$15.54	$ 4.72	6.69

For the three and nine months ended September 30, 2010, the Company recognized compensation expense of $527,085 and $1,646,176 respectively, relating to options granted in previous years, $532,907 and $927,926, respectively, relating to options granted during 2010.

For the three and nine months ended September 30, 2010, the Company recognized expense of $64,597 and $93,173, respectively, relating to options granted to non-employees during 2010.

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 are as follows:

	Nine Months Ended September 30,	
	2010	2009
Dividend yield	None	None
Expected volatility	72.16% - 75.35 %	73.12% - 86.00 %
Weighted average volatility	73.62 %	74.42 %
Risk-free interest rates	1.45 – 3.11	1.01 – 2.76
Expected life (in years)	5.0 – 6.0	2.5 – 6.0

For the three and nine months ended September 30, 2010, the Company recognized compensation expense of $251,849 and 902,147, respectively, relating to restricted stock granted in previous years. For the nine months ended September 30, 2010, the Company recognized $370,200 relating to restricted stock granted during 2010.

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

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to 2007 Warrants. The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrants agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. A total of 861,889 shares of common stock were issued pursuant to exercises of the 2007 Warrants during 2010. The 2007 Warrants are currently exercisable at $3.44 per share with 1,558,435 warrants outstanding. The shares were issued pursuant to an effective registration statement on Form S-3.

The $2,190,979 in proceeds allocated to the 2009 Warrants and the $4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the nine month period ended September 30, 2010, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of $10,164,567. The resulting warrant liability totaled $12,829,844 at September 30, 2010. The fair value of the Warrants at September 30, 2010 was determined by using an option pricing model assuming a risk free interest rate of 0.86% for the 2009 Warrants and 0.42% for the 2007 Warrants, volatility of 83.90% for the 2009 Warrants and 87.50% 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.

Money Market Funds

Cash and cash equivalents includes a money market account valued at $50,974,584.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2010, aggregated by the level in the fair value hierarchy within which those measurements fall:

Assets and Liabilities Measured at Fair Value on a Recurring Basis at September 30, 2010

	Level 1	Level 2	Level 3	Balance at September 30, 2010
Assets				
Marketable equity securities	$ 26,000	$ –	$ –	$ 26,000
Money market funds	50,974,584	–	–	50,974,584
Total Assets	$ 51,000,584	$ –	$ –	$ 51,000,584
Liabilities				
Warrant liability	$ –	$ –	$ 12,829,844	$ 12,829,844
Total Liabilities	$ –	$ –	$ 12,829,844	$ 12,829,844

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Liability
Beginning balance	$ 11,207,214
Total increase in the liability included as a charge to earnings	10,164,567
Total liability reclassified to additional paid in capital upon exercise of warrants	(8,541,937)
Ending balance	$ 12,829,844

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: Financing

In August 2010, the Company completed the sale of 5,185,000 shares of its common stock pursuant to an underwriting agreement with Canaccord Genuity. The Company received net proceeds of $33.6 million. This offering was made pursuant to an effective shelf registration (333-165677).

Note 8: Taxes

As discussed in Note 4 to the Company's audited financial statements contained in the 2009 Annual Report on Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

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

For the nine months ended September 30, 2010, the Company recorded a state capital tax benefit of $187,500. This benefit is a result of New York State legislation, which allows companies to obtain cash refunds from the New York State 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 13, 2010, the Company entered into a License, Supply and Contract Manufacturing Agreement (the "Agreement") with Synerx Pharma, LLC ("Synerx") and Bioniche Teoranta ("Bioniche Pharma") for the supply of Delcath's brand of melphalan hydrochloride for injection ("Product"). Pursuant to the Agreement, Synerx granted Delcath a limited right of reference to the Synerx Abbreviated New Drug Application for melphalan hydrochloride for injection (the "Synerx ANDA"), as incorporated into Delcath's chemosaturation system for percutaneous hepatic perfusion (the "PHP System"), in the United States (the "Territory"), and Bioniche Pharma has agreed to supply Delcath with Product. The approved Synerx ANDA and its associated files are registered to Synerx and licensed to Bioniche Pharma for manufacturing and distribution in the Territory. In accordance with the terms of the Agreement, Delcath was granted a license to reference the Synerx ANDA as part of Delcath's New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") for the PHP System. Further, during the term of the Agreement, Synerx has agreed that it will not grant a license in the Synerx ANDA to competitors of Delcath for use in the Territory in the field of chemosaturation for percutaneous hepatic perfusion.

The Agreement is effective as of October 13, 2010 and will continue for a period of seven years from the first day of the third month following the date on which Delcath receives notice of FDA approval of its NDA. The Agreement is renewable for successive one year periods upon mutual agreement of the parties. Pursuant to the terms of the Agreement, Delcath paid each of Synerx and Bioniche Pharma $250,000 upon execution and will pay each of Synerx and Bioniche Pharma $250,000 within ten days of FDA approval of Delcath's NDA. Delcath will pay Bioniche Pharma for Product ordered in accordance with the terms and conditions of the Agreement and has agreed to annual minimum Product purchase requirements.

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

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

Special Note Regarding Forward-Looking Statements

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

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the 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 system; and
- our ability to successfully negotiate and enter into agreements with strategic distribtion 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 Annual Report on Form 10-K.

We are a development stage, specialty pharmaceutical and medical device company focused on oncology. Since our inception, we have focused our efforts on the development of the Delcath system for chemosaturation therapy. Our proprietary system has been designed to administer high-dose chemotherapy and other therapeutic agents to diseased

organs or regions of the body. The Delcath system for chemosaturation therapy provides concentrated regional therapy by isolating the circulatory system of the target organ to directly deliver saturating doses of anti-cancer agents, while controlling systemic exposure to, and side effects from those agents by filtering the chemotherapeutic-laden blood prior to returning it to the patient. The Delcath system for chemosaturation therapy involves a series of three catheter insertions, each of which is made through standard interventional techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs and with a recovery period that is shorter than surgical alternatives such as resection.

Our initial focus is on cancers of the liver. Currently, the Delcath system for chemosaturation therapy is designed to deliver high doses of melphalan hydrochloride, or melphalan, directly to the liver for treatment of metastatic melanoma. In 2010, we concluded a Phase III clinical trial for the Delcath 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 system for chemosaturation therapy with melphalan in patients with primary and metastatic liver cancer. The Phase III trial was conducted under an 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 United States Food and Drug Administration, or FDA, has informed us that the Delcath system for chemosaturation therapy with melphalan will be regulated as a drug. Before we can market the Delcath system for chemosaturation therapy, we must obtain FDA approval of the drug

and device under a Section 505(b)(2) new drug application, or NDA. We initiated our rolling NDA submission to the FDA at the end of April 2010 and expect to complete the NDA application during the fourth quarter of 2010. In Europe, we expect the system to be regulated as a device. The Delcath system for chemosaturation therapy is not currently approved by the FDA or any foreign regulatory body, and it cannot be marketed in the United States or elsewhere without regulatory approval.

We believe that the Delcath system for chemosaturation therapy is a platform technology that may have broader applicability to other organs and body regions in cancer, as well as other indications. We 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.

On April 21, 2010, we announced that our Phase III clinical trial of the Delcath system for chemosaturation therapy 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 system for chemosaturation or treatment with best alternative care. Comparing treatment with the Delcath system with melphalan to best alternative care, based on independent core lab review of patient scans, the statistical analysis revealed that the Delcath system for chemosaturation therapy 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 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 system for chemosaturation therapy 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). We intend to include the results of our Phase II clinical trial in our NDA submission to the FDA, which we expect to file during the fourth quarter of 2010.

We also intend to conduct a clinical trial of the Delcath system for chemosaturation therapy with doxorubicin 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 continue to actively pursue strategic partners to develop markets in China, Korea, Japan and Europe. We are also pursuing United States pharmaceutical partners to co-develop and fund additional indications for the Delcath system for chemosaturation.

We plan to seek one or more corporate partners to market products outside the United States. We believe distribution or corporate partnering arrangements internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target. We intend to market the Delcath system for chemosaturation in the United States ourselves focusing our initial marketing efforts on the over fifty NCI-designated cancer centers in the United States, beginning with the hospitals participating 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 system for chemosaturation;
- medical oncologists who have initial responsibility for cancer patients; and
- interventional radiologists who are physicians specialized in working with catheter-based systems.

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

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. Because we have no approved product and no commercial sales, we will continue to be dependent upon existing cash, the sale of equity or debt securities, or establishing strategic alliances with appropriate partners to fund future activities. We cannot be assured that we will obtain FDA or other foreign regulatory approval for our Delcath system for chemosaturation, that we will have, or could raise, sufficient financial resources to sustain our operations pending FDA or any other foreign regulatory approval, or that, if and when the required approvals are obtained, there will be a market for our product. We expect that the amount of capital required for operations including preparation of the Company's submission to the FDA, operations at the manufacturing facility in upstate New York, and efforts to commericialize the Delcath PHP system for chemosaturation will continue to increase over the coming months. We believe that we have sufficient capital for operations through 2011.

We are a development stage company, and 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 year.

Results of Operations

Three Months Ended September 30, 2010 and September 30, 2009

We have operated at a loss for our entire history. We had a net loss for the three months ended September 30, 2010, of $9.5 million, which is a $1.9 million increase in the net loss for the same period in 2009. The increase in net loss is due to an increase of $3.7 million in total costs, which was offset by a $1.7 million change in the value of the warrant derivative instrument.

Our operating loss for the three months ended September 30, 2010 was $7.4 million, of which $1.4 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 4 of this filing. This compares to an operating loss for the three months ended September 30, 2009 of $3.8 million, of which $600,978 was non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans.

At the end of the third quarter of 2009 we had 10 full-time employees. At the end of the third quarter of 2010, we had 44 full-time employees and have expanded nearly every department throughout the Company. 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, our continued preparations for FDA and foreign regulatory approvals, research and development activity, and commercialization plans has contributed to the rise in our total costs and expenses. We anticipate continued increases in our total costs and expenses.

General and administrative expenses increased by $1.7 million, from $1.4 million during the three months ended September 30, 2009 to $3.1 million for the three months ended September 30, 2010. The Company has continued its progress in transitioning from a development stage company focused solely on research and development activites to a commercial enterprise with staff dedicated to commercializing the Delcath system for chemosaturation therapy. 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 September 30, 2010, research and development expenses increased by $2 million, from $2.3 million during the third quarter of 2009 to $4.3 million. Our recent hiring has contributed to a marked increase in research and development expenses. Our facility in Queensbury is now operational and we have expanded both our

Research and Development and Regulatory and Quality Assurance departments. Additionally, we have focused substantial efforts to completing our submission for FDA approval of the Delcath system for chemosaturation therapy for the treatment of ocular and cutaneous metastatic melanoma to the liver wth melphalan as well our efforts to prepare and submit other applications for approval of the Delcath system outside the United States.

Interest income is from our money market account and certificates of deposit. During the three months ended September 30, 2010, the Company had interest income of $2,949, as compared to $3,054 for the same period in 2009.

Nine Months Ended September 30, 2010 and September 30, 2009

We had a net loss for the nine months ended September 30, 2010, of $31.4 million, which is a $15.0 million increase in the net loss for the same period in 2009. The increase in net loss is due to an increase of $13.1 million in total costs, which includes a $1.9 million increase in warrant derivative instrument expense.

Our operating loss for the nine months ended September 30, 2010 was $21.2 million, of which $3.9 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 4 of this filing. This compares to an operating loss for the nine months ended September 30, 2009 of $8.1 million, of which $802,200 was non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans.

The remaining increase is primarily due to our recent hiring and related overhead expenses, as well as our efforts to prepare for submission to the FDA. At the end of the third quarter of 2009 we had 10 full-time employees. At the end of the third quarter of 2010, we had 44 full-time employees and have expanded every department throughout the Company. We anticipate the Company's growth to continue.

General and administrative expenses increased by $7.3 million, from $2.1 million during the nine months ended September 30, 2009 to $9.4 million for the nine months ended September 30, 2010. The Company has continued its progress in transitioning from a development stage company focused solely on research and development activites to a commercial enterprise with staff dedicated to future commercialization of the Delcath system for chemosaturation therapy. 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 nine months ended September 30, 2010, research and development expenses increased from $6.0 million during the first nine months of 2009 to $11.8 million, an increase of $5.8 million. Our recent hiring has also contributed to a marked increase in research and development expenses. Our facility in Queensbury is now operational and we have expanded both our Research and Development and Regulatory and Quality Assurance departments. Additionally, we have focused substantial efforts to completing our submission for FDA approval of the Delcath system for chemosaturation therapy.

Interest income is from our money market account and certificates of deposit. During the nine months ended September 30, 2010, the Company had interest income of $6,824, as compared to $71,982 for the same period in 2009. This decrease is principally due to market conditions which continue to yield a lower percentage of return than in previous years.

Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and we anticipate that losses will continue for the foreseeable future. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including future clinical trials; the timing and costs of making various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements overseas; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments. As we seek FDA and other foreign regulatory approvals and commence marketing and manufacturing of our product we expect that our capital expenditures will increase significantly.

Nearly all of our available funds are invested in money market accounts and certificates of deposit. At September 30, 2010, we had cash and cash equivalents of $51.8 million, as compared to $35.5 million at December 31, 2009. In addition, the Company holds $2.5 million in certificates of deposit not classified as cash equivalents.

During the nine months ended September 30, 2010, we used $16.9 million of cash in our operating activities, which compares to $7.6 million used in our operating activities during the comparable nine month period in 2009. The increase of $9.3 million is due to the recent personnel additions discussed above, our efforts to focus on preparing our submission to the FDA and other foreign regulatory agencies, and our preparations to commericialize the system. We expect that our cash allocated to operating activities will continue to increase as we aggressively move towards fully staffing our facility in upstate New York and continue to navigate the regulatory approval process. We believe we have sufficient capital to fund our operating activities through 2011.

At September 30, 2010, the Company's accumulated deficit was approximately $100.7 million. Because our business does not generate any positive cash flow from operating activities, we may need to raise additional capital in order to develop our product or to fund development efforts relating to new products. We believe that we could raise additional capital in the event that we find it in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when we need it, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from those planned because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003 along with our registered direct offering in 2007 and a public offering in November 2009. Please see the detailed discussion of our various sales of securities described in Note 3 to the Company's audited financial statements contained in the 2009 Annual Report on Form 10-K.

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

In March 2010, the Company filed a registration statement on Form S-3, which will allow the Company to offer and sell, from time to time in one or more offerings up to $100,000,000 of common stock, preferred stock, stock purchase contracts, warrants and debt securities as it deems prudent or necessary to raise capital at a later date. The registration statement became effective April 13, 2010 (333-165677). In August 2010, the Company completed the sale of 5,185,000 shares of its common stock pursuant to an underwriting agreement with Canaccord Genuity. This offering reduced the amount available under the registration statement to $66,245,650. The Company intends to use the net proceeds from any future offerings under the registration statement for general corporate purposes, including, but not limited to, funding its clinical trials, capital expenditures, working capital, repayment of debt and investments.

Critical Accounting Estimates

The Company's financial statements have been prepared in accordance with GAAP. Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's financial statements contained in the 2009 Annual Report on Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

Additionally, the Company devotes substantial resources to clinical trials and other research and development activities related to obtaining FDA and other approvals for the Delcath system for chemosaturation therapy, 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.

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

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

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

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

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

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

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of $13,303,267 in this transaction. The Company allocated $4,269,000 of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at $4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. During 2010, 861,889 of the 2007 Warrants were exercised. The 2007 Warrants are currently exercisable at $3.44 per share with 1,558,435 warrants outstanding.

The $2,190,979 in proceeds allocated to the 2009 Warrants and the $4,269,000 in proceeds allocated to the 2007 Warrants are classified as liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the nine month period ended September 30, 2010, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of $10,164,567. The resulting warrant liability totaled $12,829,844 at September 30, 2010. The fair value of the Warrants at September 30, 2010 was determined by using an option pricing model assuming a risk free interest rate of 0.86%

for the 2009 Warrants and 0.42% for the 2007 Warrants, volatility of 83.9% for the 2009 Warrants and 87.5% 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 of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing warrant liability will be credited to stockholders' equity.

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 September 30, 2010 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We have made the following changes to our internal controls over financial reporting during our fiscal quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting:

1. We began implementing an Enterprise Resource Planning ("ERP") system to fully integrate our operations. As part of this process, our financial reporting system was converted during the quarter ended September 30, 2010. We expect the system to be fully implemented by the end of the first quarter of 2011.

2. In July 2010, we hired a Staff Accountant. As our operations continue to grow, the hiring of additional accounting staff allows us to ensure we maintain the appropriate level of controls over our financial processes.

PART II:

OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

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

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

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 Principal 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.

November 1, 2010

DELCATH SYSTEMS, INC.
(Registrant)

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

Exhibit Index

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