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, 2012.

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, 35th Floor, 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 x 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 o

As of November 6, 2012, 75,075,446 shares of the Company's common stock, $0.01 par value were outstanding.

DELCATH SYSTEMS, INC.

Index

DELCATH SYSTEMS, INC.

PART I:
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Index to Financial Statements

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	September 30, 2012	December 31, 2011
Assets:		
Current assets		
Cash and cash equivalents	$ 28,298	$ 25,777
Investments – Certificates of deposit	–	4,980
Inventories	941	–
Accounts receivables	43	–
Prepaid expenses and other current assets	1,440	1,231
Total current assets	30,722	31,988
Property, plant and equipment		
Land	154	154
Building and building improvements	449	–
Furniture and fixtures	969	880
Machinery and equipment	1,435	1,371
Computer software and equipment	2,136	1,212
Leasehold improvements	1,698	1,148
	6,841	4,765
Less: accumulated depreciation	(2,556)	(1,512)
Property, plant and equipment, net	4,285	3,253
Total assets	$ 35,007	$ 35,241
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable and accrued expenses	$ 5,148	$ 6,398
Warrant liability	4,561	2,439
Total current liabilities	9,709	8,837
Deferred revenue	358	300
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2012 and December 31, 2011	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 73,422,008 and 48,237,634 shares issued and 73,393,908 and 48,209,534 outstanding at September 30, 2012 and December 31, 2011, respectively	734	482
Additional paid-in capital	212,324	172,613
Accumulated deficit	(188,150)	(146,940)
Treasury stock, at cost; 28,100 shares at September 30, 2012 and December 31, 2011	(51)	(51)
Accumulated other comprehensive income	83	–
Total stockholders' equity	24,940	26,104
Total liabilities and stockholders' equity	$ 35,007	$ 35,241

See accompanying notes to condensed consolidated financial statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statement of Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenue	$ 39	–	$ 146	–
Cost of goods sold	–	–	–	–
Gross profit	39	–	146	–
Operating expenses				
Selling, general and administrative	$ 6,960	$ 5,744	$ 21,604	$ 15,148
Research and development	5,254	6,437	20,589	15,333
Total operating expenses	12,214	12,181	42,193	30,481
Operating loss	(12,175)	(12,181)	(42,047)	(30,481)
Change in fair value of warrant liability, net	446	3,872	1,025	14,864
Interest income	9	1	16	1
Other expense and interest expense	(93)	–	(204)	–
Net loss	$ (11,813)	$ (8,308)	$ (41,210)	$ (15,616)
Common share data:				
Basic and diluted loss per share	$ (0.18)	$ (0. 18)	$ (0.72)	$ (0.35)
Weighted average number of basic and diluted common shares outstanding	67,219,224	46,961,123	56,844,697	44,315,838
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ 87	$ –	$ 83	$ –
Unrealized loss on securities	–	(3)	–	(14)
Other comprehensive income (loss), total	87	(3)	83	(14)
Comprehensive loss	$ (11,726)	$ (8,311)	$ (41,127)	$ (15,630)

See accompanying notes to condensed consolidated financial statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine months ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (41,210)	$ (15,616)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	2,159	2,921
Restricted stock compensation expense	763	438
Depreciation expense	1,044	723
Warrant liability fair value adjustment	(1,025)	(14,864)
Non-cash interest income	(3)	(1)
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	(206)	742
Decrease (increase) in inventories	(941)	–
Decrease (increase) in accounts receivables	(43)	–
Deferred revenue	58	–
Increase (decrease) in accounts payable and accrued expenses	(1,250)	1,843
Net cash used in operating activities	(40,654)	(23,814)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2,076)	(2,275)
Proceeds from maturities of short-term investments	4,980	(2,243)
Net cash provided by (used in) investing activities	2,904	(4,518)
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	40,188	23,674
Net cash provided by financing activities	40,188	23,674
Effect of exchange rate on cash	83	–
(Decrease) increase in cash and cash equivalents	2,521	(4,658)
Cash and cash equivalents at beginning of period	25,777	45,621
Cash and cash equivalents at end of period	$ 28,298	$ 40,963
Supplemental cash flow information:		
Cash paid for interest	$ –	$ –
Supplemental non-cash activities:		
Cashless exercise of stock options and shares surrendered upon restricted stock vesting	$ –	$ (61)
Fair value of warrants issued and exercised	$ 3,147	$ –

See accompanying notes to condensed consolidated financial statements.

DELCATH SYSTEMS, INC.

Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2012 and 2011

Note 1: Description of Business and Summary of Significant Accounting Policies

Delcath Systems, Inc. (the "Company") is a 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 announced that its randomized Phase III clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® delivery system in April 2011 and for the second generation hemofiltration cartridge for CHEMOSAT in April 2012. In October 2012, the Company satisfied all of the requirements to affix the CE Mark to its CHEMOSAT device system for use with doxorubicin hydrochloride injection, providing a regulatory pathway for CHEMOSAT with doxorubicin hydrochloride injection for countries in Asia that accept CE Marking as part of their national regulatory requirements. The Company submitted its New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) on August 15, 2012, seeking approval for commercial sale of its chemosaturation system with melphalan in the treatment of patients with unresectable metastatic melanoma in the liver. The Company's NDA was accepted for filing by the FDA, and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. The Company has not yet received FDA approval for commercial sale of its system in the United States. Delcath transitioned from a development stage company to a commercial organization with operational activities in April 2012. Accordingly, reporting as a development stage company is no longer deemed necessary.

The Company has incurred losses since inception and anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management anticipates that additional working capital will be required to continue operations. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

Note 2: Basis of Condensed Consolidated Financial Statement Presentation

The accompanying condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles 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 preparation of condensed consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's condensed consolidated financial statements. The condensed consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated. 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, 2012 and 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 unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2011, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 as filed with the Securities and Exchange Commission (the "SEC") on March 6, 2012.

Note 3: Summary of Significant Accounting Policies

Use of Estimates
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 condensed consolidated 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 operating expense accruals. 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.

Selling, General and Administrative Costs
Selling, general and administrative costs include personnel costs and related expenses for the Company's sales, marketing, general management and administrative staff, recruitment, costs related to the Company's commercialization efforts in Europe, professional service fees, professional license and organizational fees, business development and certain general legal activities.

Research and Development Costs
Research and development costs include the costs of materials used for R&D and clinical trials, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

Revenue Recognition
Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Inventory
Prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of September 30, 2012 includes finished goods and components relating to Generation Two of the Delcath Hepatic CHEMOSAT® Delivery System that have been purchased since April 2012. Therefore, as is common for companies transitioning from the development stage to commercial, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company's cost of goods sold will be reduced accordingly.

Deferred Revenue Recognition
Deferred revenue on the accompanying condensed consolidated balance sheets includes payment received for product sales to a distributor and payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied and will recognize the deferred revenue related to the research and distribution agreement over the expected obligation period of the agreement once this amount is reasonably determinable.

Recently Adopted Accounting Pronouncements
In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04 which was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05 which provides new guidance on the presentation of comprehensive income. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and instead requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The adoption of this ASU only requires a change in the format of the current presentation. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's condensed consolidated financial statements.

In December 2011, the Financial Accounting Standards Board ("FASB") issued ASU 2011-12, "*Comprehensive Income*". This update amends certain pending paragraphs in ASU No. 2011-05 "*Presentation of Comprehensive Income*", to effectively defer only those changes that relate to the presentation of reclassification adjustments out of accumulated other comprehensive income for annual and interim financial statements for public, private, and non-profit entities. The Company adopted this guidance on January 1, 2012, and its adoption did not significantly impact the Company's condensed consolidated financial statements.

Note 4: Cost of Goods Sold

The majority of the Company's inventory was purchased prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, including all of the components used in the kits sold during the nine months ended September 30, 2012. Additionally, the kits were built during the quarter ended March 31, 2012 and accordingly, all labor and overhead related to the kits was expensed during the first quarter. As a result, the costs of sales related to recognized and deferred revenue was $0.

DELCATH SYSTEMS, INC.

Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2012 and 2011

Note 5: Inventories

Inventories consist of:

	September 30, 2012	December 31, 2011
Raw materials	$ 178	$ -
Work-in-process	518	-
Finished goods	245	-
Totals	$ 941	$ -

Note 6: 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 6,500,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In May 2012, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 2,300,000 shares, from 4,200,000 to 6,500,000 upon a favorable vote by the Company's stockholders. 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.

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, 2012 is as follows:

	Stock Option Activity under the Plans		
	Stock Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Life (Years)**
Outstanding at December 31, 2011	4,129,749	$ 5.09	6.38
Granted	1,203,452	3.81	
Expired	(400,000)	4.95	
Forfeited	(99,148)	4.98	
Outstanding at September 30, 2012	4,834,053	4.78	7.11

For the three and nine months ended September 30, 2012, the Company recognized compensation expense of approximately $0.3 million and $1.1 million, respectively, relating to options granted in previous years and $0.5 million and $1.0 million, respectively, relating to options granted during 2012.

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,	
	2012	2011
Dividend yield	None	None
Expected volatility	77.37% - 84.47%	72.16% - 75.35%
Weighted average volatility	79.87%	73.62%
Risk-free interest rates	0.78% - 1.49%	1.45% - 3.11%
Expected life (in years)	6.0	5.0 - 6.0

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life of the stock options on the grant date. The expected holding period was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under FASB ASC 718. This method of determining the expected holding period was utilized because the Company does not have sufficient historical experience from which to estimate the period.

Restricted stock activity for the nine month period ended September 30, 2012 is as follows:

	Restricted Stock Activity	
	Restricted Stock	**Weighted Average GrantDate FairValue**
Non-vested at December 31, 2011	193,532	5.84
Granted	428,920	2.84
Vested	(91,910)	5.85
Forfeited	(15,431)	4.19
Non-vested at September 30, 2012	515,111	3.38

For the three and nine months ended September 30, 2012, the Company recognized compensation expense of $0.1 million and $0.4 million, respectively, relating to restricted stock granted in previous years. For the three and nine months ended September 30, 2012, the Company recognized approximately $0.2 million and $0.4 million, respectively, relating to restricted stock granted during 2012.

Note 7: Assets and Liabilities Measured at Fair Value

Derivative warrant liability

The Company allocated part of the proceeds of a private placement and two public offerings of the Company's common stock to warrants issued in connection with those 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 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.

DELCATH SYSTEMS, INC.

Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2012 and 2011

In May 2012, the Company completed the sale of 15,333,340 shares of its common stock and the issuance of warrants to purchase 4,600,002 common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. At September 30, 2012, the 2012 Warrants were exercisable at $1.65 per share with 4,600,002 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants 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 proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants (see below). As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's May 31, 2012 sale of common stock and warrants. At September 30, 2012, the 2009 Warrants were exercisable at $1.33 per share with 1,043,478 warrants outstanding. The 2009 Warrants 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") 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 those proceeds to the 2007 Warrants (see below). In accordance with the provisions of the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's May 31, 2012 sale of common stock and warrants and became exercisable at $1.49 per share with 3,392,592 warrants outstanding. The 2007 Warrants expired on September 21, 2012. Approximately 3.0 million warrants were exercised during the quarter ended September 30, 2012. The remaining liability after the warrant exercises was credited to pre-tax derivative instrument income.

The $3.4 million in proceeds allocated to the 2012 Warrants and the $2.2 million in proceeds allocated to the 2009 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, 2012, the Company recorded pre-tax derivative instrument income of $1.0 million. The resulting derivative instrument liabilities totaled $4.6 million at September 30, 2012. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at September 30, 2012 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	83.54%	85.83%
Risk-free interest rates	0.28%	0.21%
Expected life (in years)	2.7	1.7

Money Market Funds
Cash and cash equivalents includes a money market account valued at $2.0 million.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2012, 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, 2012
(in thousands)

	Level 1	Level 2	Level 3	Balance at September 30, 2012
Assets				
Money market funds	$ 1,967	-	-	$ 1,967
Total Assets	$ 1,967	-	-	$ 1,967
Liabilities				
Warrant liability	$ -	-	$ 4,561	$ 4,561
Total Liabilities	$ -	-	$ 4,561	$ 4,561

DELCATH SYSTEMS, INC.

Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2012 and 2011

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
(in thousands)

	Warrant Liability
Beginning balance	$ 2,439
Total change in the fair value of the liability included in earnings	(1,025)
Fair value of warrants issued	4,055
Fair value of warrants exercised or expired	(908)
Ending balance	$ 4,561

Note 8: Common Stock

In May 2012, the Company completed the sale of 15,333,340 shares of its common stock and the issuance of warrants to purchase 4,600,002 common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

On December 29, 2011, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC to sell shares of the Company's common stock, par value $.01 per share, having aggregate sales proceeds of $39,750,000, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. As of September 30, 2012, the Company had sold approximately 6.5 million shares of its common stock through the program for net proceeds after related expenses of approximately $14.6 million. The net proceeds were used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. As of September 30, 2012, there was approximately $24.5 million available under this program.

Note 9: 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, 2012 and 2011 upon exercise or conversion that were not included in the computation of net loss per share totaled 10,477,533 and 6,739,948 shares, respectively.

Note 10: Taxes

As discussed in Note 4 to the Company's audited financial statements contained in the 2011 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 income tax in the United States, the Republic of Ireland, and certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS"), international tax authorities, or any states in connection with income taxes. The periods from December 31, 2004 to December 31, 2011 remain open to examination by the IRS and state tax authorities. The period ending December 31, 2011 remains open to examination by the international tax authorities. Also note that the federal, state, and international 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.

DELCATH SYSTEMS, INC.

Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2012 and 2011

For the nine months ended September 30, 2012, the Company recorded a state capital tax benefit of approximately $53,000. This benefit includes New York State investment and employment credits. The investment tax credits are generated from investments in buildings and tangible property located and used in New York State for production or research and development activities. The employment credits are generated by the creation of emerging technology jobs in New York State. Since the benefits are not determined based on income, the net benefit is reflected as a component of general and administrative expenses.

Note 11: Subsequent Events

During the fourth quarter through November 6, 2012, the Company sold approximately 1.7 million shares of our common stock under the Sales Agreement through an “at the market” equity offering program for net proceeds of approximately $3.0 million. The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. As of November 6, 2012, the Company has approximately $21.5 million remaining under the program.

On October 15, 2012, Delcath announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection. The FDA has designated the NDA for standard review.

On November 1, 2012, Delcath announced that the U.S. Food and Drug Administration assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013, for substantive review of the Company's New Drug Application (NDA) of its proprietary chemosaturation system with melphalan hydrochloride for injection.

The Company completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no other subsequent events requiring disclosure in or adjustment to these financial statements.

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

The following discussion and analysis of the Company's 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 the audited financial statements and notes thereto as of and for the year ended December 31, 2011 included in the Company's 2011 Annual Report on Form 10-K to provide an understanding of its 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 Delcath's business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology 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 the Company's research and development programs;
- the Company's estimates regarding sufficiency of cash resources, anticipated capital requirements and need for additional financing;
- the commencement of future clinical trials and the timing and results of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- the Company's ability to successfully source certain components of the system and enter into supplier contracts;
- the Company's ability to successfully manufacture and supply the Delcath chemosaturation system;
- the Company's ability to successfully commercialize the Delcath Chemosaturation system; and
- the Company's 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 the Company's 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, Delcath does 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. 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 announced that its randomized Phase III clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® delivery system in April 2011 and for the second generation hemofiltration cartridge for CHEMOSAT in April 2012. In October 2012, the Company satisfied all of the requirements to affix the CE Mark to its CHEMOSAT device system for use with doxorubicin hydrochloride injection, providing a regulatory pathway for CHEMOSAT with doxorubicin hydrochloride injection for countries in Asia that accept CE Marking as part of their national regulatory requirements. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company submitted its New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) on August 15, 2012, seeking approval for commercial sale of its chemosaturation system with melphalan in the treatment of patients with unresectable metastatic melanoma in the liver. The Company's NDA was accepted for filing by the FDA, and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. The Company will continue to work with the FDA to complete its review with the goal of obtaining approval for commercial sale of its proprietary chemosaturation system with melphalan. The Company has not yet received FDA approval for commercial sale of its system in the United States.

Challenge of Treating Liver Dominant Disease

There are two types of liver cancer: primary and metastatic. Primary liver cancer (hepatocellular carcinoma or HCC) originates in the liver and is particularly prevalent in populations where the primary risk factors for the disease (hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants) are present. Metastatic, or secondary, liver cancer is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological function of the liver, including processing nutrients from food and filtering toxins from the blood, it is common for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize in their liver. In the United States, metastatic liver cancer is more prevalent than primary liver cancer.

The Delcath system for hepatic chemosaturation allows the administration of concentrated regional chemotherapy to the liver. This “whole organ” therapy is administered by first isolating the circulatory system of the liver, saturating the entire organ with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. The Delcath system involves three catheters placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, deliver a 30 minute infusion of chemotherapeutic agent (currently melphalan hydrochloride) directly to the liver, and collect drug-laden blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of chemotherapeutic agent in the blood, thereby minimizing systemic exposure to the drug and related side-effects before the filtered blood is returned to the patient’s circulatory system.

The procedure is minimally invasive and repeatable, allowing for multiple courses of treatment with chemotherapeutic drugs and the potential for concomitant use in conjunction with other cancer therapies. The Company believes that the Delcath chemosaturation system may play an important role in the management of cancers in the liver, potentially providing time and additional options for treatment of a patient’s primary disease. The Company also believes that the Delcath system is a platform technology that in the future may include the use of other drugs to treat cancers in the liver, as well as for the treatment of cancers in other organs and regions of the body.

European Market Commercialization

In April 2011, the Company obtained the right to affix the CE Mark to its first generation commercial product: the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT System). Delcath believes the CHEMOSAT System may ultimately fulfill an annual unmet clinical need for as many as 59,000 patients with cancers in the liver in this region. In the EEA, the CHEMOSAT System is regulated as a medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return.

In the EEA, the Company is focusing its initial commercialization efforts on seven target markets: Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. The Company believes these countries represent a majority of the total potential liver cancer market in the EEA. The Company's commercialization strategy for these markets involves the establishment of initial training and launch centers at prestigious cancer hospitals. Medical teams at these centers are trained in the performance of the CHEMOSAT procedure and proctored for their initial cases by experienced physicians, and are provided additional logistical support by Delcath. The Company believes that as the CHEMOSAT teams at these centers gain experience, they will form a European base of key opinion leadership that will help educate other physicians about the potential of chemosaturation therapy with CHEMOSAT and foster initial market acceptance. To further drive adoption, the Company is using a combination of direct and indirect sales channels to market and distribute the CHEMOSAT System in Europe. The Company has recently entered into exclusive distribution agreements for Italy and Spain. In addition, the Company has retained Quintiles to provide a third party medical science liaison force to educate medical oncologists in the target markets about the CHEMOSAT system. To support commercialization efforts, the Company established its EU headquarters in Galway, Ireland.

In November 2011, the Company announced that it had entered into its first initial training and launch agreement with the European Institute of Oncology (IEO) in Milan, Italy. As of the end of the third quarter, the Company has signed a total of 13 such agreements with leading European cancer centers, and has established a presence in all seven of its target markets. Patients treated thus far include those with inoperable liver-dominant metastases from ocular melanoma, cutaneous melanoma, breast cancer, gastric cancer and cholangiocarcinoma.

In April 2012, the Company announced it received CE Mark approval for the Generation Two hemofiltration cartridge of the CHEMOSAT System. The Generation Two system has demonstrated filter efficiency greater than 98% during drug infusion of melphalan in an in vivo study; the same study also showed that the Generation Two filter removes fewer blood platelets. Upon approval of the Generation Two filter, the Company began supplying its early launch and training centers exclusively with the Generation Two CHEMOSAT system.

Applications for interim reimbursement have been submitted in Germany, Italy and the UK and the Company expects a response by first quarter of 2013. Delcath is also supporting efforts of treatment centers to pursue patient specific insurance funding in these countries as well as in Spain. In the other target countries, reimbursement pathways have been identified and are being actively pursued.

Regulatory

International Regulations

The Company recently changed its Notified Body in Europe and as part of this change the CHEMOSAT System was reclassified from a Class III medical device to a Class IIb medical device. The primary difference between Class III and Class IIb is that for Class IIb medical devices the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to lodge an application for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

On October 22, 2012, the Company announced that it had satisfied all of the requirements to affix the CE Mark to its Hepatic CHEMOSAT Delivery System with doxorubicin hydrochloride ("CHEMOSAT System with doxorubicin"). CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Application of the CE Mark for the CHEMOSAT System with doxorubicin provides Delcath with a regulatory pathway for certain countries in Asia that accept CE Marking as part of their national regulatory requirements. Doxorubicin is an established chemotherapeutic agent commonly used globally to treat hepatocellular carcinoma (HCC) via trans-arterial chemoembolization (TACE) and is widely used to treat HCC in Asia, which is where the Company sees the market opportunity for our CHEMOSAT system with doxorubicin injection. In China, these requirements include conducting a local clinical trial and approval by the China State Food and Drug Administration (SFDA). Delcath intends to seek approvals for the CHEMOSAT System with doxorubicin in key Asian markets such as China and South Korea. The Company does not intend to market the CHEMOSAT System with doxorubicin in the European Economic Area at this time.

Having previously obtained the CE Mark for the CHEMOSAT System with melphalan, the Company believes the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the EEA and the United States. Delcath recently received regulatory approval for the second generation CHEMOSAT System in Australia and has completed the product notification process in New Zealand. The Company has submitted applications for regulatory approval as a device for the CHEMOSAT System in Hong Kong, South Korea, Singapore, Canada and Israel and Delcath intends to submit regulatory applications in Mexico, Argentina, Brazil, Russia, India, Japan, China, and Taiwan. Delcath is in the process of determining the regulatory pathway in some of these countries subject to negotiations with the applicable health authority. It is Delcath's intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath CHEMOSAT System, where appropriate. Delcath Systems Limited's facility in Galway, Ireland has obtained certificates of free sale from the Irish Medicines Board as many markets require country of origin manufacturing, such as Mexico, Argentina, Brazil, Japan, China, and Taiwan, as a prerequisite to obtain regulatory approval.

United States

In the United States, the Delcath chemosaturation system for the administration of melphalan hydrochloride is considered a combination drug and device product and is regulated as a drug by the U.S. Food and Drug Administration (FDA). In August 2012, the Company submitted its Section 505(b)(2) New Drug Application (NDA), to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. The Company's NDA was accepted for filing by the FDA, and has been designated for standard review with a PDUFA goal date of June 15, 2013.

In addition to the NDA submission, the Company submitted to the FDA an amendment to its Investigational New Drug application to include the Generation Two system in the FDA's Expanded Access Program (EAP), as well as all future clinical trials and compassionate use cases. The Company announced acceptance of these amendments on June 18, 2012, and expects the first centers to begin treating patients under the EAP by the end of 2012.

Results of Operations

The Company recorded the first sales of its CHEMOSAT System in Europe during the quarter ended June 30, 2012, resulting in net sales of $0.1 million. During the quarter ended September 30, 2012, the Company recorded sales of $0.1 million, $58,000 of which is deferred until the Company fulfills its obligations under the distribution agreement and the distributor is able to ship kits to the centers it anticipates servicing. As discussed in Note 4 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, the Company did not recognize any cost associated with the recognized or deferred revenue.

As Delcath continues to expand its commercialization in Europe, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several quarters. This volatility will be related to several factors, including: the expected use of third party distributors, whose purchase prices will be lower than direct to end user customer prices; the gradual increase in cost of goods sold as the Company exhausts raw materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and an improvement in efficiencies as the Company increases its production of the CHEMOSAT system.

Three Months Ended September 30, 2012 and September 30, 2011

The Company had a net loss for the three months ended September 30, 2012, of $11.8 million, which is a $3.5 million increase in the net loss for the same period in 2011. The increase in net loss is primarily due to a $3.4 million change in the fair value of the warrant liability.

The Company's operating loss for the three months ended September 30, 2012 was $12.2 million, of which $1.0 million is non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans as discussed in more detail in Note 6 of this filing. This compares to an operating loss for the three months ended September 30, 2011 of $12.2 million, of which $0.9 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

At September 30, 2012 the Company had 95 full-time employees compared to 74 at September 30, 2011. The increase in total costs is commensurate with this growth, which has led to an increase in payroll and overhead expenses. Additionally, the Company's ongoing commercialization efforts in the European Union and continued efforts to prepare its submission to the FDA have contributed to the increase in total costs and expenses. As the Company continues to advance its business strategy, it will continue to incur losses for the foreseeable future.

For the three months ended September 30, 2012, selling, general and administrative expenses increased to $7.0 million from $5.7 million for the three months ended September 30, 2011. A significant portion of the increase is related to the Company's continued expansion, particularly as Delcath has continued executing on its commercialization plans by hiring staff for sales and support positions across Europe. This has led to an increase in personnel-related expenses, as well as all other expenses related to maintaining an office and supporting employees.

For the three months ended September 30, 2012, research and development expenses decreased to $5.3 million from $6.4 million for the three months ended September 30, 2011. The reduction in expenses is primarily related to the Company's transition from a development stage company to a commercial organization. Purchases of inventory are now capitalized rather than being expensed as research and development materials. Additionally, there was a reduction in expenses related to the preparation of the NDA submission.

Interest income is from a money market account and interest earned on operating accounts. During the three months ended September 30, 2012, the Company had interest income of $8,629, as compared to $537 for the same period in 2011.

Nine Months Ended September 30, 2012 and September 30, 2011

The Company had a net loss for the nine months ended September 30, 2012, of $41.2 million, which is a $25.6 million increase in the net loss for the same period in 2011. The increase in net loss is primarily due to an increase of $11.7 million in total costs and a $13.8 million change in the fair value of the warrant liability.

The Company's operating loss for the nine months ended September 30, 2012 was $42.0 million, of which $2.9 million is non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans as discussed in more detail in Note 6 of this filing. This compares to an operating loss for the nine months ended September 30, 2011 of $30.5 million, of which $3.4 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

At September 30, 2012 the Company had 95 full-time employees compared to 74 at September 30, 2011. The increase in total costs is commensurate with this growth, which has led to an increase in payroll and overhead expenses. Additionally, the Company's ongoing commercialization efforts in the European Union, continued efforts to prepare its submission to the FDA, as well as research and development activities, such as the recently approved Generation Two filter, have contributed to the increase in total costs and expenses. As the Company continues to invest in product commercialization, R&D and clinical activities it will continue to incur operating losses for the foreseeable future.

For the nine months ended September 30, 2012, selling, general and administrative expenses increased to $21.6 million from $15.1 million for the nine months ended September 30, 2011. A significant portion of the increase is related to the Company's continued expansion, particularly as Delcath has continued executing on its commercialization plans by hiring staff for sales and support positions across Europe. This has led to an increase in personnel-related expenses, as well as all other expenses related to maintaining an office and supporting employees.

For the nine months ended September 30, 2012, research and development expenses increased to $20.6 million from $15.3 million for the nine months ended September 30, 2011. The increase in expenses is primarily related to global regulatory efforts including continued preparation of the NDA submission to the FDA, securing CE Mark for the Generation Two filter and the expansion of addressable markets through the pursuit of additional regional regulatory approvals, as well as the training and deployment of third party medical science liaisons.

Interest income is from a money market account, interest earned on operating accounts and certificates of deposit. During the nine months ended September 30, 2012, the Company had interest income of $15,818, as compared to $1,202 for the same period in 2011.

Liquidity and Capital Resources

The Company's future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming year. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At September 30, 2012, the Company had cash and cash equivalents totaling $28.3 million, as compared to $41.0 million at September 30, 2011. During the nine months ended September 30, 2012, the Company used $40.7 million of cash in its operating activities, which compares to $23.8 million used for operating activities during the comparable nine month period in 2011. The increase of $16.9 million is primarily driven by NDA submission related costs, expenses related to the Company's ongoing commercialization efforts in Europe, an increase in compensation related expenses as the Company grew from 74 employees at September 30, 2011 to 95 employees at September 30, 2012, and research and development activities, such as the recently approved Generation Two and doxorubicin filters. The Company believes it has access to sufficient capital to fund operating activities for the next twelve months. Assuming Delcath receives FDA approval in 2013, the Company anticipates additional resources will be required to support full U.S. commercialization.

Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fully commercialize the product or to fund development efforts relating to additional indications. The Company believes it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's 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 its development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, the Company's assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of clinical trials and costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, public offerings in 2000, 2003, 2009, 2010, 2011 and 2012, registered direct offerings in 2007 and 2009, and an “at the market” equity offering program initiated in 2012. For a detailed discussion of the Company’s various sales of securities and the “at the market” equity offering program see Note 3 to the Company’s audited financial statements contained in the 2011 consolidated financial statements in the 2011 Annual Report on Form 10-K and Note 8 to the Company’s condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

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 and July 2011 public offerings detailed in Note 3 to the Company’s audited financial statements contained in the 2011 Annual Report on Form 10-K and for establishing an "at the market" equity offering program detailed in Note 8 to the Company’s condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q. As of September 30, 2012, Delcath had approximately $24.5 million available under its “at the market” equity offering program. 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 its products, funding of clinical trials, capital expenditures and working capital.

In December 2011, the Company filed a registration statement on Form S-3 with the SEC, which allowed 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 deemed prudent or necessary to raise capital at a later date. The registration statement became effective on February 13, 2012 (333-178819). The Company used this registration statement for its May 2012 public offering detailed in Note 8 to the Company’s condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. The Company filed a new shelf registration statement on Form S-3 with the SEC, which became effective on October 9, 2012 (333-183675). This new shelf replaces the shelf registration filed in December 2011 and 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.

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 2011 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 the Company’s choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company’s financial statement estimates are significant or critical.

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

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

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

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

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

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 7 to the Company's condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under FASB ASC 820.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the value of its investments.

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 May 2012, the Company completed the sale of 15,333,340 shares of its common stock and the issuance of warrants to purchase 4,600,002 common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. At September 30, 2012, the 2012 Warrants were exercisable at $1.65 per share with 4,600,002 warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants 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 proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the warrant liability. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's March 19, 2012 sale of common stock under the "at the market" equity offering program as discussed in more detail in Note 8 of this filing. At September 30, 2012, the 2009 Warrants were exercisable at $1.33 per share with 1,043,478 shares outstanding. The 2009 Warrants 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" 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 the 2007 Warrants. Following the Company's May 31, 2012 sale of common stock and warrants, the 2007 Warrants were exercisable at $1.49 per share with 3,392,592 warrants outstanding. The 2007 Warrants expired on September 21, 2012. Approximately 3.0 million warrants were exercised during the quarter ended September 30, 2012. The remaining liability after the warrant exercises was credited to pre-tax derivative instrument income.

The $3.4 million in proceeds allocated to the 2012 Warrants and the $2.2 million in proceeds allocated to the 2009 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, 2012, the Company recorded pre-tax derivative instrument income of $1.0 million. The resulting derivative instrument liabilities totaled $4.6 million at September 30, 2012. Management expects that the warrants will either be exercised or expire worthless. The fair value of the Warrants at September 30, 2012 was determined by using an option pricing model assuming the following:

	2012 Warrants	2009 Warrants
Expected volatility	83.54%	85.83%
Risk-free interest rates	0.28%	0.21%
Expected life (in years)	2.7	1.7

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that Delcath's disclosure controls and procedures as of June 30, 2012 (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 the Company's 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 management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There was no change in our internal control over financials reporting that occurred during the quarter ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II:
OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Delcath's 2011 Annual Report on 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 7, 2012

DELCATH SYSTEMS, INC.
(Registrant)

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

Exhibit Index

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** Filed herewith.

*** Furnished herewith.

EXHIBIT 31.1

Certification
of Principal Executive Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Eamonn P. Hobbs, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2012

/s/Eamonn P. Hobbs
Eamonn P. Hobbs
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification
of Principal Financial Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Graham G. Miao, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2012

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

EXHIBIT 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eamonn P. Hobbs, the President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2012

/s/Eamonn P. Hobbs
Eamonn P. Hobbs
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Graham G. Miao, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2012

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